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Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Medical Devices; Classification Hematology and Pathology

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 864]

[Docket No. 78N-1833]

Classification of Hematology and Pathology Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency is proposing general rules applicable to the classification of all hematology and pathology devices. The Medical Device Amendments of 1976 require the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual hematology and pathology devices, which are being published elsewhere in this issue of the **Federal Register**. The preamble also describes the activities of the Hematology Device Classification Panel and the Pathology Device Classification Panel, FDA advisory committees that make recommendations to FDA concerning the classification of hematology and pathology devices.

DATES: Comments by November 13, 1979. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Hematology and pathology devices are subject to labeling requirements in § 809.10 (21 CFR 809.10) for in vitro diagnostic products. As defined in § 809.3(a) (21 CFR 809.3(a)), in vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. These products are intended for use in collecting, preparing, and examining specimens taken from the human body. Before the Medical Device Amendments of 1976, FDA regarded in vitro diagnostic products as drugs or devices, or as combinations of drugs and devices. Since the enactment of the amendments, with their expanded definition of "device" in section 201(h) of the act (21 U.S.C. 321(h)), FDA regards in vitro diagnostic products as devices.

Certain in vitro diagnostic products are also biological products subject to section 351 of the Public Health Service Act (42 U.S.C. 262). Hematology devices that are also biological products include blood grouping sera, antihuman globulin sera, leukocyte typing sera, hepatitis B antigen, antibody to hepatitis B antigen, blood group specific substances, and reagent red blood cells. Establishments manufacturing these products are subject to licensure by the Bureau of Biologics, FDA, under section 351 of the Public Health Service Act. The Hematology Device Classification Panel has not yet made classification recommendations concerning these products. However, certain of these products have in vitro diagnostic uses for which licensing is not required. The Hematology Panel made recommendations concerning those uses, which FDA is publishing elsewhere in this issue of the **Federal Register** in the proposal for classification of blood group substances of nonhuman origin for in vitro diagnostic use (Docket No. 78N-1922). This proposal excludes licensable blood group specific substances. Similarly, the proposal for classification of systems for the identification of hepatitis B antigen (Docket No. 78N-1934) excludes licensable hepatitis B antigen and antisera to hepatitis B antigen. The proposal for classification of quality control kits for blood reagents (Docket No. 78N-1938) covers antisera to various blood group antigens, antihuman globulin sera, and red blood cells, none of which are licensable.

Among the hematology devices that are subject to classification proposals in this issue of the **Federal Register** are a number of devices that are used in establishments that manufacture human blood and blood products. The classifications of devices used in these establishments are being codified in Subpart J of proposed Part 864 (21 CFR Part 864, Subpart J). Establishments that manufacture human blood and blood products include human blood and

plasma donor centers, blood banks, transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for blood product establisments. These establishments are already regulated by the Bureau of Biologics under regulations in Parts 606, 607, and 640 (21 CFR Parts 606, 607, and 640). FDA has decided that it is appropriate for devices used only in these establishments to be regulated under the provisions of the Federal Food, Drug, and Cosmetic Act that apply to devices, as well as under section 351 of the Public Health Service Act, where applicable, and the regulations in Parts 606, 607, and 640.

Activities of Panels

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Hematology Device Classification Panel and the Pathology Device Classification Panel were originally chartered on October 15, 1974, as the Hematology/Pathology Subcommittee of the Diagnostics Products Advisory Committee.

On August 9, 1976, the Subcommittee was divided and rechartered as the Hematology Device Classification Panel and the Pathology Device Classification Panel to reflect new responsibilities under the amendments. The agency directed each Panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, each Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the Panels' deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of hematology and pathology devices. The Panels also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panels submitted to FDA preliminary reports of their recommendations. The reports included rosters of current and former Panel members and consultants and listed all meeting dates. The agency placed copies of the report in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, and announced their availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual hematology and pathology device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

List of Hematology and Pathology Devices

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of hematology and pathology devices. The Panels supplemented the list using their members' knowledge of hematology and pathology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 864 in Title 21 of the Code of Federal Regulations. Part 864 will consist of sections identifying each hematology or pathology device with a brief narrative description and stating the classification of that device. A list of the hematology and pathology devices appears elsewhere in this preamble.

Individual Hematology and Pathology Device Classification Regulations

Elsewhere in this issue of the **Federal Register**, the agency is issuing 108 individual proposed regulations to classify each hematology and pathology device. The agency is proposing to classify 46 hematology and pathology devices into class I (general controls), 55 devices into class II (performance standards), 6 devices into class III (premarket approval), and one document proposes to classify the electromagnetic type of a device into class III and the nonelectromagnetic type of the device into class II. FDA also is publishing the recommendations of the Panels regarding these devices, as required by section 513(c)(2) and (d)(1) of the act.

Published Panel Recommendations

Each published Panel recommendation concerning a hematology or pathology device includes the information described below.

1. *Identification.* Both the Panel recommendation and proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 864.1 (21 CFR 864.1), any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807) cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes that the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87) and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panels did not recommend that any device be exempted at this time from section 519 of the act, the Pathology Device Classification Panel did recommend that the manufacturers of several class I devices be exempted from good manufacturing practice regulations (and thus from the records and reports requirements in these regulations) in the manufacture of these devices. The Hematology Device Classification Panel recommended that manufacturers of one class I device be

exempted from the premarket notification requirements of section 510(k). The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the agency is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant of a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporing or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied on clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. No. 94–853, 94th Congress, 2d Session 40 (1967)). The agency has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual hematology and pathology device proposed regulations. The FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by hematology or pathology devices, the Panels recognized that few devices are completely free of risk. The Panels listed the risks they considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by hematology and pathology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify a hematology or pathology device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 864 in which the device classification will be codified.

The FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that a Panel recommends be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignement of a priority for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II or class III, the Panels compared the devices with other hematology or pathology devices on the basis of information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panels recommended assignment of a "high priority" only to those class II or class III devices that the Panels believed should receive the agency's immediate attention.

The FDA is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. At a later date, however, the agency will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the

priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether they are considered to be of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (at least 30 months) following classification, during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510, registration; section 519, records and reports; and section 520(f), good manufacturing practices.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency has proposed to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within this exempt generic type of device.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978. At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt a device from § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program, as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that

device manufacturers have adequate systems for complaint investigation and followup, all such manufacturers are required to comply with the complaint file requirements of § 820.198. All device manufacturers also are required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f), but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than §§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than § 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

List of Hematology and Pathology Devices

The following is a list of the hematology and pathology devices that FDA is proposing to classify, the section and subpart of Part 864 in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Subpart B—Biological Stains

Section	Device	Docket No.	Class
864.1850	Dye or chemical solution stains	78N-1834	I
864.1875	Dye powder stains	78N-1835	I

Subpart C—Cell and Tissue Culture Products

864.2220	Synthetic cell and tissue culture media and components	78N-1836	I
864.2240	Cell and tissue culture supplies and equipment	78N-1373	I
864.2260	Chromosome culture kit	78N-1837	I
864.2280	Cultured animal and human cells	78N-1838	I
864.2360	Mycoplasma detection media and components	78N-1839	I
864.2800	Animal and human sera	78N-1840	I
864.2875	Balanced salt solutions or formulations	78N-1841	I

Subpart D—Pathology—Instrumentation and Accessories

864.3010	Tissue processing equipment	78N-1842	I
864.3250	Specimen transport and storage container	78N-1843	I
864.3300	Cytocentrifuge	78N-1844	I
864.3400	Device for sealing micro-sections	78N-1845	I
864.3600	Microscopes and accessories	78N-1846	I
864.3800	Automated slide strainer	78N-1847	I
864.3875	Automated tissue processor	78N-1848	I

Subpart E—Specimen Preparation Reagents

864.4010	General purpose reagent	78N-1849	I
864.4400	Enzyme preparations	78N-1850	I

Subpart F—Automated and Semi-Automated Hematology Devices

864.5200	Automated cell counter	78N-1851	II
864.5220	Automated differential cell counter	78N-1852	III
864.5240	Automated blood cell diluting apparatus	78N-1853	I
864.5260	Automated cell locating device	78N-1854	II
864.5300	Red cell indices device	78N-1855	II
864.5350	Microsedimentation centrifuge	78N-1856	I
864.5400	Coagulation instrument	78N-1857	II
864.5425	Multipurpose system for in vitro coagulation studies	78N-1858	II
864.5600	Automated hematocrit instrument	78N-1859	II
864.5620	Automated hemoglobin system	78N-1860	II
864.5680	Automated heparin analyzer	78N-1861	III
864.5700	Automated platelet aggregation system	78N-1862	II
864.5800	Automated sedimentation rate device	78N-1863	I
864.5850	Automated slide spinner	78N-1864	I
864.5950	Blood volume measuring device	78N-1865	II

Subpart G—Manual Hematology Devices

864.6100	Bleeding time device	78N-1866	II
864.6150	Capillary blood collection tube	78N-1867	I
864.6160	Manual blood cell counting device	78N-1868	I
864.6400	Hematocrit measuring device	78N-1869	II
864.6475	Iron kinetics test	78N-1870	II
864.6550	Occult blood test	78N-1871	II
864.6600	Osmotic fragility test	78N-1872	I
864.6650	Platelet adhesion test	78N-1873	I
864.6675	Platelet aggregometer	78N-1874	II
864.6750	Red cell survival test	78N-1875	II
864.6800	Erythrocyte sedimentation rate test	78N-1876	I

Subpart H—Hematology Kits and Packages

864.7040	Adenine nucleotide assay	78N-1877	I
864.7060	Antithrombin III assay	78N-1878	II
864.7100	Cell enzyme assay	78N-1879	II
864.7140	Activated whole blood clotting time test	78N-1880	II
864.7250	Erythropoietin assay	78N-1881	III
864.7275	Euglobulin lysis time test	78N-1882	II
864.7290	Qualitative and quantitative factor deficiency test	78N-1883	II
864.7300	Fibrin monomer paracoagulation test	78N-1884	II
864.7320	Fibrin split products assay	78N-1885	II
864.7340	Fibrinogen determination system	78N-1886	II
864.7360	Erythrocytic glucose-6-phosphate dehydrogenase assay	78N-1887	II
864.7375	Glutathione reductase assay	78N-1888	II
864.7400	Hemoglobin A_2 assay	78N-1889	II
864.7415	Abnormal hemoglobin assay	78N-1890	II
864.7425	Carboxyhemoglobin assay	78N-1891	II
864.7440	Electrophorectic hemoglobin analysis system	78N-1892	II
864.7455	Fetal hemoglobin assay	78N-1893	II
864.7490	Sulfhemoglobin assay	78N-1895	II
864.7500	Whole blood hemoglobin assay	78N-1896	II
864.7525	Heparin assay	78N-1897	II
864.7660	Leukocyte alkaline phosphatase test	78N-1898	I
864.7675	Leukocyte peroxidase test	78N-1899	I
864.7720	Prothrombin consumption test	78N-1900	II
864.7735	Prothrombin-proconvertin test and thrombotest	78N-1901	II
864.7750	Prothrombin time test	78N-1902	II
864.7825	Sickle cell test	78N-1903	II
864.7875	Thrombin time test	78N-1904	II
864.7900	Thromboplastin generation test	78N-1905	I
864.7925	Partial thromboplastin time test	78N-1906	II

Subpart I—Hematology Reagents and Stains

864.8030	Hematology stains	78N-1907	I
864.8100	Bothrops atrox reagent	78N-1908	II
864.8150	Calibrator for cell indices	78N-1909	III
864.8165	Calibrator for hemoglobin and hematocrit measurement	78N-1910	II
864.8175	Calibrator for platelet counting	78N-1911	II
864.8185	Calibrator for red cell and white cell counting	78N-1912	II
864.8200	Blood cell diluent	78N-1913	I
864.8500	Lymphocyte separation medium	78N-1914	I
864.8540	Red cell lysing reagent	78N-1915	I
864.8625	Hematology quality control mixture	78N-1916	II
864.8950	Russell viper venom reagent	78N-1917	I

Subpart J—Products Used in Establishments That Manufacture Blood and Blood Products

864.9050	Blood bank supplies	78N-1918	I
864.9100	Container for collection and processing of blood and blood components.	78N-1919	III
864.9125	Vacuum-assisted blood collection system	78N-1920	I
864.9145	Processing system for frozen blood	78N-1921	III
864.9160	Blood group substances of nonhuman origin for in vitro diagnostic use.	78N-1922	II
864.9175	Automated blood grouping and antibody test system	78N-1923	II
864.9185	Blood grouping view box	78N-1924	I
864.9195	Blood mixing and weighing device	78N-1925	I
864.9205	Blood and plasma warming device	78N-1926	II, III
864.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use.	78N-1927	I
864.9245	Automated blood cell separator	78N-1928	III
864.9275	Blood bank centrifuge for in vitro diagnostic use	78N-1929	I
864.9285	Automated cell-washing centrifuge for immuno-hematology	78N-1930	II
864.9300	Automated Coombs test system	78N-1931	II
864.9320	Copper sulfate solution for specific gravity determinations	78N-1932	I
864.9400	Stabilized enzyme solution	78N-1933	II
864.9500	System for the identification of hepatitis B antigen	78N-1934	I
864.9550	Lectins and protectins	78N-1935	II
864.9575	Environmental chamber for storage of platelet concentrate	78N-1936	II
864.9600	Potentiating media for in vitro diagnostic use	78N-1937	II
864.9650	Quality control kit for blood banking reagents	78N-1938	II
864.9700	Blood storage refrigerator and blood storage freezer	78N-1939	II
864.9750	Heat-sealing device	78N-1940	I
864.9875	Transfer set	78N-1942	I

Devices Considered By Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by Panels other than the Hematology Device Classification Panel or the Pathology Device Classification Panel:

1. The Clinical Chemistry Device Classification Panel recommended that colorimetric methods for the detection of occult blood in urine and enzymatic methods for the detection of occult blood in urine be classified into class II. The Hematology Device Classification Panel recommended that occult blood reagents be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying occult blood tests into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

2. The Clinical Chemistry Device Classification Panel recommended that NADP reduction (ultraviolet) and visual semi-quantitative (colorimetric) methods to measure glucose-6-phosphate dehydrogenase activity and electrophoretic methods to measure glucose-6-phosphate dehydrogenase isoenzyme activity be classified into class II. The Hematology Device Classification Panel recommended that catalase inhibition, methemoglobin reduction, and quantitative methods to measure glucose-6-phosphate dehydrogenase activity be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying methods for the measurement of erythrocytic glucose-6-phosphate dehydrogenase activity into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

3. The Clinical Chemistry Device Classification Panel recommended that fluorescence (visual observation, qualitative ultraviolet) methods for the measurement of glutathione reductase activity be classified into class II. The Hematology Device Classification Panel recommended that red cell glutathione be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying methods for the measurement of glutathione reductase activity into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

4. The Immunology Device Classification panel recommended that antithrombin III immunoassays be classified into class II. The Hematology Device Classification Panel recommended that antithrombin III quantitation be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying methods for antithrombin III quantitation into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

5. The Immunology Device Classification Panel recommended that immunoassays to detect fibrinogen and split products, including those employing FITC, peroxidase, and rhodamine, be classified into class II. The Hematology Device Classification Panel recommends that fibrinogen tests and fibrinogen determination standards and controls be classified into class II. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying fibrinogen determination systems into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

6. The Anesthesiology Device Classification Panel recommended that electromagnetic blood warmers be classified into class III and that nonelectromagnetic blood warmers be classified into class II. The Hematology Device Classification Panel recommended that blood and plasma warming devices be classified into class II. The agency has determined that these devices should be classified in a single regulation. FDA is proposing that nonelectromagnetic blood and plasma warming devices be classified into class II and that electromagnetic blood and plasma warming devices be classified into class III. FDA is publishing the two Panels' recommendations elsewhere in this issue of the **Federal Register.**

7. The Hematology Device Classification Panel and the Clinical Chemistry Panel made classification recommendations concerning the following devices:

Blood collection tray
Vacuum sample tube with anticoagulant
Blood tube mixer
General laboratory timer

The Hematology Device Classification Panel's recommendations and proposed classification regulations for the devices listed above will be published when FDA publishes the recommendations of the Clinical Chemistry Panel.

8. The Hematology Device Classification Panel recommended that crystal violet, giemsa stain, new methylene blue stain, and toluidine blue be classified into class I. The Pathology Device Classification Panel recommended that dye powder stains be classified into class I. The Microbiology Device Classification Panel recommended that microbiology stains be classified into class I. The agency has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying dye powder stains into class I and is publishing the three Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

9. The Pathology Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Centrifuge, general	Clinical chemistry.
Resin, ion exchange	Clinical toxicology.

The Pathology Device Classification Panel's recommendations and proposed classification regulations for the devices listed above will be published when the agency publishes the recommendations of the other panels that reviewed the devices.

Skin Preparation Materials

The Hematology Device Classification Panel recommended that skin preparation materials be classified into class I. A skin preparation material is a prepacked product containing sterilizing solution (e.g., alcohol swabs) used to prepare the skin of a blood donor before blood is drawn or of a patient before a blood transfusion. Because these materials are, for now, being regulated as drugs rather than as devices, FDA is not publishing a proposal to classify these materials.

Immersion Oil

The Hematology Device Classification Panel recommended that immersion oil be classified into class I. Immersion oil is a fluid that is placed between an oil immersion microscope objective and a microscope slide to improve the resolution of the objective. Because FDA has determined that immersion oil is not a "device" under section 201(h) of the act (21 U.S.C. 321(h)), FDA is not publishing a proposal to calssify this product.

Vitamin B_{12}

Absorption Test (Schilling's Test)

The Hematology Device Classification Panel recommended that the vitamin B_{12} absorption test (Schilling's test) be classified into class II. The test consists of the oral administration of radioisotope-labeled (usually ^{57}Co or ^{60}Co) vitamin B_{12} (cyanocobalamin) followed by administration of a flushing dose of unlabeled B_{12}. The radioactivity of the patient's urinary output is then measured over a 24-hour period to determine the status of B_{12} absorption by the patient's gastrointestinal tract. Because the test is an in vivo diagnostic test and therefore a "drug" under section 201(g)(1) of the act, FDA is not publishing a proposal to classify this test as a device.

Environmental Impact

The FDA has carefully considered the environmental effects of proposed § 864.1 and of the proposed hematology and pathology device classification regulations, and because the proposed actions will not significantly affect the quality of the human environment has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)), and under authority delegated to the Commissioner of Food and Drugs (21 U.S.C. 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 864, Subpart A, to read as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

Subpart A—General Provisions

Sec.
864.1 Scope.

Authority.— Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding proposed § 864.1. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27812 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1834]

Medical Devices; Classification of Dye and Chemical Solution Stains

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dye and chemical solution stains into class I (general controls). The FDA is also publishing the recommendations of the Pathology Device Classification Panel and the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel and the Hematology Device

Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of dye and chemical solution stains:

1. Identification: Dye and chemical solution stains are either solutions of one or more synthetic and/or natural dyes or solutions of one or more nondye chemicals used to stain cells and tissues for diagnostic histopathology and hematology. The Pathology Device Classification Panel reviewed these products under the names "chemical and chemical solution stains" and "dye solution stains." The Hematology Device Classification Panel reviewed these products under the name "periodic acid Schiff stain."

2. Recommended classification: The Pathology Device Classification Panel recommends that the devices reviewed under the name "chemical and chemical solution stains" be classified into class I (general controls) with exemptions from records and reports and good manufacturing practices requirements. The Pathology Device Classification Panel recommends that the devices reviewed under the name "dye solution stains" be classified into class I (general controls) with no exemptions. The Hematology Device Classification Panel recommends that the product reviewed under the name "periodic acid schiff stain" be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that dye and chemical solution stains be classified into class I because the hazards of these products are minimal when used by persons trained in their use. Both Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Pathology Device Classification Panel recommends that the products reviewed under the name "chemical and chemical solutions" be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i) because current manufacturing practices in the manufacture of the device and user experience with the device indicate that the application of the GMP regulation will not improve the safety and effectiveness of the device. The Panel also recommends that dye and chemical solution stains be exempt from the records and reports requirements of section 519 of the act (21 U.S.C. 360i).

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' familiarity and clinical experience with these devices, and on the devices' history of satisfactory performance.

5. Risks to health: The Pathology Device Classification Panel has not identified any risks to health. The Hematology Device Classification Panel has identified the following risk to health: Inappropriate diagnosis or therapy: Poor staining characteristics may contribute to failure to detect abnormal cell types, inability to differentiate reactive from malignant cells, improper classification of a leukemic process, or inability to classify an anemic process.

Proposed Classification

FDA agrees with the recommendations of the Pathology Device Classification Panel and the Hematology Device Classification Panel and is proposing that dye and chemical solution stains be classified into class I (general controls). The agency believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these products.

FDA disagrees with the Panels' recommendation that manufacturers of dye and chemical solution stains be exempt from the records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirement, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panels' recommendation that manufacturers of dye and chemical solution stains be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt, in the manufacture of the devices, from all requirments in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of dye and chemical solution stains must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of dye and chemical solution stains must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate divice-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart B and new § 864.1850, to read as follows:

Subpart B—Biological Stains.

§ 864.1850 Dye and chemical solution stains.

(a) *Identification:* Dye and chemical solution stains are either solutions of one or more synthetic and/or natural dyes or solutions of one or more nondye chemicals used to stain cells and tissues for diagnostic histopathology and hematoloty.

(b) *Classification:* Class I (general controls). The devices are exempt from the good manufacturing practice

regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirments concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all coments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27613 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N–1835]

Medical Devices; Classification of Dye Powder Stains

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dye powder stains into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel, the Microbiology Device Classification Panel, and the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, the Microbiology Device Classification Panel, and the Hematology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of dye powder stains:

1. Identification: Dye powder stains are synthetic or natural dyes that are used in the staining of cells and tissues for diagnostic histopathology and hematology. The Pathology Device Classification Panel reviewed these products under the names "certified dye powder stains" and "noncertified dye powder stains." Certified dye powder stains have been tested and certified by the Biological Stain Commission by satisfying specific physiochemical standards and in-use tests. Noncertified dye powder stains have either not been tested or have been tested but not certified by the Biological Stain Commission. The Hematology Device Classification Panel reviewed these products under the names "crystal violet for hematology," "giemsa stain," "new methylene blue stain," and "toluidine blue." The Microbiology Device Classification Panel reviewed these products under the name "all microbiological stains."

2. Recommended classification: The Pathology Device Classification Panel recommends that the products reviewed under the name "certified dye powder stains" be classified into class I (general controls) with exemptions from good manufacturing practice requirements under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The Pathology Device Classification Panel recommends that the products reviewed under the name "non-certified dye powder stains" be classified into class I (general controls) with exemption from the good manufacturing practice regulations under section 520(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(f)). The Hematology Device Classification Panel recommends that "crystal violet for hematology," "giemsa stain," "new methylene blue stain," and "toluidine blue" be classified into class I with no exemptions. The Microbiology Device Classification Panel recommends that "all microbiological stains" be classified into class I with no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that dye powder stains be classified into class I (general controls) because these products present no risks to health when used by persons trained in their use. All three Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Pathology Device Classification Panel recommends that the devices reviewed under the name "certified dye powder stains" be exempt from records and reports regulations because certification by the Biological Stain Commission is satisfied by meeting specific physiochemical standards and in-use tests, and controls are used to help detect reagent failure in the more critical diagnostic tests. The Pathology Device Classification Panel also recommends that dye powder stains, whether or not certified, by exempt from good manufacturing practice requirements because current manufacturing practices in the manufacture of the devices and user experience with the devices indicate that the application of the GMP regulation will not improve the safety and effectiveness of the devices.

4. Summary of data on which the recommendation is based: The Pathology Device Classification Panel, the Hematology Device Classification Panel, and the Microbiology Device Classification Panel based their recommendations upon their Panel members' familiarity and clinical experience with the devices, and on the devices' history of satisfactory performance.

5. Risks to health: The Pathology Device Classification Panel and the Microbiology Device Classification Panel did not identify any risks to health. The Hematology Device Classification Panel identified the following risks to health: Inappropriate diagnosis or therapy: Poor staining characteristics may contribute to failure to detect abnormal cell types, inability to differentiate reactive from malignant cells, improper classification of a leukemic process, or inability to classify an anemic process.

Proposed Classification

FDA agrees with the recommendations of the Pathology Devices Classification Panel, the Microbiology Device Classification

Panel, and the Hematology Device Classification Panel and is proposing that dye powder stains be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

FDA disagrees with the Panels' recommendation that manufacturers of dye powder stains be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panels' recommendation that manufacturers of dye powder stains be exempt from the device good manufacturing practive (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of dye powder stains must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of dye powder stains must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart B by adding new § 864.1875 as follows:

§ 864.1875 Dye powder stains.

(a) *Identification.* Dye powder stains are synthetic or natural dyes that are used in the staining of cells and tissues for diagnostic histopathology and hematology.

(b) *Classification.* Class I (general controls). The devices are exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27614 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1836]

Medical Devices; Classification of Synthetic Cell and Tissue Culture Media and Components

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying synthetic cell and tissue culture media and components into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of synthetic cell and tissue culture media and components:

1. Identification: Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts, etc.) that are essential for the survival and development of cell lines of humans and other animals.

2. Recommended classification: Class I (general controls). The Panel

recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that synthetic cell and tissue culture media and components be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Although these reagents are susceptible to batch-to-batch variations in their manufacturing process due to the biological nature of the components, the Panel believes that conformity by manufacturers with FDA's device good manufacturing practice regulation should control these variations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with these products and upon the products' history of satisfactory performance.

5. Risks to health: Delayed diagnosis: The failure of these devices to provide sufficient nutritional factors in a cell and tissue culture system may require that a given diagnostic procedure be repeated, causing a delay in diagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that synthetic cell and tissue culture media and components be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart C including new § 864.2220 as follows:

Subpart C—Cell and Tissue Culture Products

§ 864.2220 Synthetic cell and tissue culture media and components.

(a) *Identification.* Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g. amino acids, vitamins, inorganic salts, etc.) that are essential for the survival and development of cell lines of humans and other animals.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27615 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1373]

Medical Devices; Classification of Cell and Tissue Culture Supplies and Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cell and tissue culture supplies and equipment into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that these devices be classified into class I. The effect of classifying a device into class I is to require that the devices meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cell and tissue culture supplies and equipment:

1. Identification: Cell and tissue culture supplies and equipment are devices that are used to examine, propogate, nourish, or grow cells and tissue cultures. These include such articles as slide culture chambers, perfusion and roller apparatus, cell culture suspension systems, and tissue culture flasks, disks, tubes, and roller bottles.

2. Recommended classification: Class I (general controls). The Panel recommends that these products be exempted from good manufacturing practice regulations.

3. Summary of reasons for recommendation: The Panel recommends that cell and tissue culture supplies and equipment be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. The Panel recommends that these devices be exempt from the good manufacturing practice regulation because current manufacturing practices in the manufacture of the devices and user experience with the devices indicate that the application of the GMP regulation will not improve the safety and effectiveness of the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with these devices, and upon the devices' history of satisfactory performance.

5. Risks to health: None specified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cell and tissue culture supplies and equipment be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

In response to the Panel's recommendation that manufacturers of cell and tissue culture supplies and equipment be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that

a manufacturer of these devices who does not label or otherwise represent them as sterile be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of cell and tissue culture supplies and equipment, even when they are not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of cell and tissue culture supplies and equipment must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of cell and tissue culture supplies and equipment that are labeled or otherwise represented as sterile is in the manufacture of these devices, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart C by adding new § 864.2240 as follows:

§ 864.2240 Cell and tissue culture supplies and equipment.

(a) *Identification.* Cell and tissue culture supplies and equipment are devices that are used to examine, propagate, nourish, or grow cells and tissue cultures. These include such articles as slide culture chambers, perfusion and roller apparatus, cell culture suspension systems, and tissue culture flasks, disks, tubes, and roller bottles.

(b) *Classification.* Class I (general controls). If the devices are not labeled or otherwise represented as sterile, they are exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27616 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1837]

Medical Devices; Classification of Chromosome Culture Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying chromosome culture kits into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classfying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chromosome culture kits:

1. Identification: A chromosome culture kit is a device containing the necessary ingredients (e.g., Minimum Essential Media (MEM) or McCoy's 5A culture media, phytohemagglutinin, fetal calf serum, antibiotics, and heparin) used to culture tissues for diagnosis of congenital chromosome abnormalities.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that chromosome culture kits be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Although the performance of these products is susceptible to batch-to-batch variations in their production, the Panel believes that conformity by manufacturers with FDA's device good manufacturing practice regulation should control these variations.

4. Summary of data on which the recommendation is based: The Panel based its recommendations upon the Panel members' familiarity and clinical experience with the product and upon the product's history of satisfactory performance.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of these products to perform satisfactorily may result in a misdiagnosis of chromosomal abnormality. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk, unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel recommendations and is proposing that chromosome culture kits be classified into class I (general controls) with no exemptions. The

Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the product.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart C by adding new § 864.2260 as follows:

§ 864.2260 Chromosome culture kit.

(a) *Identification.* A chromosome culture kit is a device containing the necessary ingredients (e.g., Minimum Essential Media (MEM) of McCoy's 5A culture media, phytohemagglutinin, fetal calf serum, antibiotics, and heparin) used to culture tissues for diagnosis of congenital chromosome abnormalities.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27617 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1838]

Medical Devices; Classification of Cultured Animal and Human Cells

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cultured animal and human cells into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this porposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cultured animal and human cells:

1. Identification: Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cultured animal and human cells be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. Although cultured animal and human cells are susceptible to batch-to-batch variations in their production, the Panel believes that conformity by manufacturers with FDA's device good manufacturing practice regulation should control these variations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with this device and the product's history of satisfactory performance.

5. Risks to health: Misdiagnosis: Failure of the cell line to support the growth of suspected viral pathogens could result in a misdiagnosis because the viral agent(s) suspected of causing a disease would not be detected.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that cultured animal and human cells be classifed into class I (general controls) with no exemption. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart C by adding new § 864.2280 as follows:

§ 864.2280 Cultured animal and human cells.

(a) *Identification.* Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27618 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1839]

Medical Devices; Classification of Mycoplasma Detection Media and Components

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mycoplasma detection media and components into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments. FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Helath, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mycoplasma detection media and components:

1. Identification: Mycoplasma detection media and components are products that are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures. The Pathology Device Classification Panel reviewed these products under the names "mycoplasma detection kit" and "mycoplasma detection media."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the products reviewed under the names "mycoplasma detection media" and "mycoplasma detection kit" be classified into class I (general controls) because these devices present no risks to health. The devices are used as a quality control component of a cell culture system and are not used directly for the diagnosis of disease. The Panel believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness for these products.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with this device, and the products' history of satisfactory performance.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel recommendations and is proposing that mycoplasma detection media and components be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness for these products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 865 be amended in Subpart C by adding new § 864.2360 as follows:

§ 864.2360 Mycoplasma detection media and components.

(a) *Identification.* Mycoplasma detection media and components are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all coments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27619 Filed 9-10-79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1840]

Medical Devices; Classification of Animal and Human Sera

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying animal and human sera into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of animal and human sera:

1. Identification: Animal and human sera are biological products, obtained from the blood of humans or other animals, that provide the necessary

growth-promoting nutrients in a cell culture system.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that animal and human sera be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. Although these products are susceptible to batch-to-batch variations in nutritional properties and contamination by indigenous agents during their manufacture, the Panel believes that the manufacturer's conformity with good manufacturing practices and labeling requirements under class I (general controls) should control these problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with these products, and upon the products' history of satisfactory performance.

5. Risks to health: Delay in diagnosis. The failure of sera to provide sufficient growth-promoting factors in a cell culture system may require that a given diagnostic procedure be repeated, causing a delay in diagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that animal and human sera be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart C by adding new § 864.2800 as follows:

§ 864.2800 Animal and human sera.

(a) *Identification.* Animal and human sera are biological products, obtained from the blood of humans or other animals, that provide the necessary growth-promoting nutrients in a cell culture system.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above ofice between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27620 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1841]

Medical Devices; Classification of Balanced Salt Solutions or Formulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying balanced salt solutions or formulations into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of balanced salt solutions or formulations:

1. Identification: A balanced salt solution or formulation is a defined mixture of salts and glucose in a simple medium. This device is included as a necessary component of most cell culture systems.

This media component controls for pH, osmotic pressure, energy source, and inorganic ions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that balanced salt solutions or formulations be classified into Class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these products. These products present minimal risks to health because they are used as a component of a cell culture system and are not used directly for the diagnosis of disease.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' familiarity and clinical experience with this demand upon the products' history of satisfactory performance.

5. Risks to health: Delayed diagnosis: The failure of balanced salt solutions to provide sufficient growth promoting factors in a cell culture system may require that a given diagnostic procedure be repeated, causing a delay in diagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that balanced salt solutions or formulations be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart C by adding new § 864.2875 as follows:

§ 864.2875 Balanced salt solutions or formulations.

(a) *Identification.* A balanced salt solution or formulation is a devined mixture of salts and glucose in a simple medium. This device is included as a necessary component of most cell culture systems. This media component controls for pH, osmotic pressure, energy source, and inorganic ions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27621 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1842]

Medical Devices; Classification of Tissue Processing Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tissue processing equipment into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel and the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel and the Hematology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of tissue processing equipment:

1. Identification: Tissue processing equipment consists of devices used to prepare human tissue specimens for diagnostic histological examination by processing the specimens through the various stages of decalcifying, infiltrating, sectioning, and mounting on microscope slides. The Pathology Device Classification Panel considered this type of product under the names "decalcifying devices," "paraffin dispensers," "flotation baths," "infiltrators," "imbedding containers," "microtomes and accessories," "microscope slides and coverslips, " and "slide-warming lamps and tables." The Hematology Device Classification Panel considered the classification of "microscope slides and coverslips."

2. Recommended classification: The Pathology Device Classification Panel recommends that tissue processing equipment be classified into class I (general controls) with exemption from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The Hematology Device Classification Panel recommends that the product reviewed under the name "microscope slides and coverslips" be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Pathology Device Classification Panel recommends that tissue processing equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Pathology Device Classification Panel also recommends that these devices be exempt from FDA's device good manufacturing practice regulation under section 520(f) of the act because current manufacturing practices in the manufacture of the device and user experience with the device indicate that the application of the GMP regulation will not improve the safety and effectiveness of the device. The Hematology Device Classification Panel recommends that the devices reviewed under the name "microscope slides and coverslips" be classified into class I because they present no risks to health when used by trained personnel. The Hematology Device Classification Panel also believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Pathology Device Classification Panel and the Hematology Device Classification Panel based their recommendations on the Panel members' familiarity and clinical experience with these devices, and on the device's history of satisfactory performance.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the recommendation of the Panels and is proposing that tissue processing equipment be classified into class I (general controls) with no exemptions. The Commissioner believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner disagrees with the Panel's recommendation that manufacturers of tissue processing equipment be exempt from the good manufacturing practice regulation under section 520(f) of the act. The Commissioner believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will prevent production of tissue processing equipment having defects that could cause failure and harm to users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart D, including new § 864.3010 as follows:

Subpart D—Pathology—Instrumentation and Accessories

§ 864.3010 Tissue processing equipment.

(a) *Identification.* Tissue processing equipment consists of devices used to prepare human tissue specimens for diagnostic histological examination by processing the specimens through the various stages of decalcifying, infiltrating, sectioning, and mounting on microscope slides.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27622 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1843]

Medical Devices Classification of Specimen Transport and Storage Containers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying specimen transport and storage containers into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of specimen transport and storage containers:

1. Identification: A specimen transport and storage container is a device used to contain biological specimens during storage and transport within and between clinics and laboratories in such an environment that the specimen can effectively be used for histological or cytological examination. The Panel reviewed these products under the names "specimen transport and storage containers" and "temperature controlled specimen transport and storage containers".

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Reasons for recommendation: The Panel recommends that specimen transport and storage containers be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness for these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' familiarity and clinical experience with these products, and on a history of satisfactory product performance.

5. Risks to health: (a) Contamination: Any leakage or breakage of the container may cause contamination of laboratory, clinic, or personnel by any infectious organism in the specimen. (b) Misdiagnosis: Biological specimens, e.g., amniotic fluid or fetal tissue, may have a toxic reaction with the material of which the container is made, causing aberrations of the specimen. Contamination of the container may also cause specimen aberrations with the production of artifacts (tissues that have been altered from their natural state), which make the specimen unusable for diagnosis. (c) Delay in diagnosis: Damage to the specimen by failure to maintain it at a specified temperature can cause physiological changes in the specimen and require the health professional to obtain a new specimen, with a consequent delay in diagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that specimen transport and storage containers be classified into class I with no exemptions. The Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3250 as follows:

§ 864.3250 Specimen transport and storage container.

(a) *Identification.* A specimen transport and storage container is a device used to contain biological specimens during storage and transport within and between clinics and laboratories in such an environment that the specimen can effectively be used for histological or cytological examination.

(b) *Recommended classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27623 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N-1844]

Medical Devices; Classification of Cytocentrifuges

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cytocentrifuges into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. the effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cytocentrifuges:

1. Identification: A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the cytocentrifuge be classified into class I because the device presents no hazards to health. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's familiarity and clinical experience with the product, and on the product's history of satisfactory performance.

5. Risks to health: None specified.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that cytrocentrifuges be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3300 as follows:

§ 864.3300 Cytocentrifuge.

(a) *Identification.* A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27624 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1845]

Medical Devices; Classification of Devices for Sealing Microsections

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying devices for sealing microsections into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of devices for sealing microsections:

1. Identification: A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that devices for sealing microsections be classified into class I

because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. This device presents minimal risks to health because the examiner can easily determine whether it is effective by simple inspection of the end product.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' familiarity and clinical experience with these devices, and on the product's history of satisfactory performance.

5. Risks to health: (a) Delay in diagnosis: An instrument malfunction can result in an incomplete sealing of the microscope slide and possibly render a tissue specimen unusable for examination. (b) Unnecessary surgical procedures: Specimen damage or loss can result from an instrument malfunction causing the need to obtain an additional biopsy specimen. This additional biopsy would require additional surgical procedures and delay the diagnosis.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that devices for sealing microsections be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3400 as follows:

§ 864.3400 Device for sealing microsections.

(a) *Identification.* A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27825 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1846]

Medical Devices; Classification of Microscopes and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microscopes and accessories into class I (general controls). The FDA is also publishing the recommendations of the Pathology Device Classification Panel and the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel and the Hematology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of microscopes and accessories:

1. Identification: Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for examination. Variations of microscopes and accessories (through a change in light source) used in clinical laboratories include the following: (a) Phase contrast microscopes, which permit visualization of unstained preparations by altering the phase relationship of light that passes around the object and through the object. (b) Fluorescence microscopes, which permit examination of specimens stained with fluorochromes that fluoresce under ultraviolet light. (c) Inverted stage microscopes, which permit examination of tissue cultures or other biological specimens in bottles or tubes with the light source mounted above the specimens. The Pathology Device Classification Panel reviewed these products under the names "microscope condensers," "microscope lamps," "fluorescent UV microscope," "tissue culture inverted stage microscope," "light microscope," "phase contrast microscope," and "microscope stages." The Hematology Device Classification Panel reviewed these products under the name "microscope."

2. Recommended classification: Class I (general controls). The Pathology Device Classification Panel recommends that there be no exemptions. The Hematology Device Classification Panel recommends that microscopes be exempted from section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

3. Summary of reasons for recommendation: The Pathology Device Classification Panel and the Hematology Device Classification Panel recommend that microscopes and accessories be classified into class I because these devices present no hazards to health. The Panels believe that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these devices. The Hematology Device Classification Panel recommends that microscopes be exempt from registration, device listing, and premarket notification under section 510 of the act because the Panel believes that compliance by the manufacturers with the requirements of section 510 of the act is not necessary for the protection of the public health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the panel members' familiarity and clinical experience with these devices, and on a history of satisfactory performance.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with both Panel recommendations and is proposing that microscopes and accessories be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness for the device.

The Commissioner disagrees, however, with the Hematology Device Classification Panel's recommendation that manufacturers of microscopes be exempt from registration, device listing, and premarket notification under section 510 of the act. Under section 510(g)(4) of the act, the Commissioner may exempt a manufacturer from compliance with section 510 of the act only upon a finding that compliance is not necessary for the protection of the public health. In the case of microscopes, the Commissioner cannot make the required finding. To protect the public health, the agency needs to require manufacturers of this device to register and to list their products with FDA, so that the agency can identify the firms and products that it regulates and can conduct necessary inspections and investigations concerning safety, effectiveness, adulteration, or misbranding. Premarket notification by these manufacturers assures that FDA learns of new products, and of significant modification of existing products, for which premarket approval is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3600 as follows:

§ 864.3600 Microscopes and accessories.

(a) *Identification.* Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for examination. Variations of microscopes and accessories (through a change in the light source) used in clinical laboratories include the following:

(1) Phase contrast microscopes, which permit visualization of unstained preparations by altering the phase relationship of light that passes around the object and through the object.

(2) Fluorescence microscopes, which permit examination of specimens stained with fluorochromes that fluoresce under ultraviolet light.

(3) Inverted stage microscopes, which permit examination of tissue cultures or other biological specimens contained in bottles or tubes with the light source mounted above the specimen.

(b) *Recommended classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27828 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1847]

Medical Devices; Classification of Automated Slide Stainers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated slide stainers into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel and the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (FHA–305), Food and Drug Administation, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel and the Hematology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of automated slide stainers:

1. Identification: An automated slide stainer is a device used to stain histology, cytology, and hematology slides for diagnosis. The Pathology Device Classification Panel considered this device under the names "immersion type slide stainer" and "contact type slide stainer." The Hematology Device Classification Panel considered this device under the name "automated slide stainer."

2. Recommended classification: The Pathology Device Classification Panel and the Hematology Device Classification Panel recommended that the automated slide stainer be classified into class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Pathology Device Classification Panel and the Hematology Device Classification Panel recommend that the automated slide stainer be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This product presents minimal risks to health because the examiner can easily determine whether the device is effective by a simple inspection of the end product.

4. Summary of data on which the recommendation is based: The Pathology Device Classification Panel and the Hematology Device Classification Panel based their recommendation on the Panel members' familiarity and clinical experience with these devices and on the product's history of satisfactory performance.

5. Risks to health: Both Panels identified the following risks to health: (a) Delayed diagnosis: A malfunction in the staining qualities of the product can result in artifacts (tissues that have been altered from their natural state), which make the slide difficult to read or unusable for diagnosis. Diagnosis could be delayed, expecially if an additional

specimen is needed for examination. (b) Unnecessary surgical procedures: A device malfunction may cause damage to the specimen making it unusable for diagnosis and resulting in additional surgical procedures to obtain a new specimen for examination.

Proposed Classification

The Commissioner agrees with the recommendations of the Pathology Device Classification Panel and the Hematology Device Classification Panel and is proposing that automated slide stainers be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3800 as follows:

§ 864.3800 Automated slide stainer.

(a) *Identification.* An automated slide stainer is a device used to stain histology, cytology, and hematology slides for diagnosis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27627 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N–1848]

Medical Devices; Classification of Automated Tissue Processors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated tissue processors into class I (general controls). The FDA is also publishing the recommendation of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel an FDA advisory committee, made the following recommendation with respect to the classification of automated tissue processors:

1. Identification: An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the automated tissue processor be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' familiarity and clinical experience with these devices, and on the devices' history of satisfactory performance.

5. Risks to health: (a) Delay in diagnosis: A product malfunction can result in an improperly fixed tissue specimen, which may be unusable for staining and examination. If an additional specimen is needed, the diagnosis may be delayed. (b) Unnecessary surgical procedures: Specimen damage or loss can result from a product malfunction requiring an additional biopsy specimen to be obtained. Additional surgical procedures and a delay in diagnosis may result.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the automated tissue processor be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart D by adding new § 864.3875 as follows:

§ 864.3875 Automated tissue processor.

(a) *Identification.* An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27628 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1849]

Medical Devices; Classification of General Purpose Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying general purpose reagents into class I (general controls). The proposed regulation would apply to cytological preservatives, decalcifying reagents, fixatives and adhesives, tissue processing reagents, isotonic solutions, and pH buffers. The FDA is also publishing the recommendation of the Pathology Device Classification Panel and the Hematology Device Classification Panel that these devices be calssified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel and the Hematology Device Classification Panel, FDA advisory committee, made the following recommendation with respect to the classification of general purpose reagents:

1. Identification: A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare and examine specimens from the human body for diagnostic histopathology and hematology, and that is not labeled or promoted for medical use or for a specific diagnostic application. General purpose reagents include cytological preservatives, decalcifying reagents, fixatives and adhesives, tissue processing reagents isotonic solutions, and pH buffers. The Pathology Device Classification Panel reviewed these products under the names "cytological preservatives," "decalcifying reagents," "fixatives," and "reagents for dehydrating, clearing, imbedding, and mounting." The Hematology Device Classification Panel considered the classification of isotonic solutions and pH buffers.

2. Recommended classification: The Pathology Device Classification Panel recommends that products reviewed under the names cytological preservatives, decalcifying reagents, and fixatives be classified into class I (general controls) with no exemptions. The Pathology Device Classification Panel recommends that reagents for dehydrating, clearing, imbedding, and mounting be classified into class I (general controls) with exemption from records and reports and good manufacturing practice requirements under sections 519 and 520(f), respectively, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i and 360j(f)). The Hematology Device Classification Panel recommends that isotonic solutions and pH buffers be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Pathology Device Classification Panel recommends that the products included in the category of general purpose reagents be classified into class I because the hazards associated with the use of these products are minimal when they are used by persons trained in their use. The Panel believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these products. The Panel recommends that "reagents for dehydrating, clearing, imbedding and mounting" be exempt from the good manufacturing practice regulation (GMP) under section 520(f) of the act and the records and reports requirements under section 519 of the act because current manufacturing practices in the manufacture of the device and user experience with the device indicate that the application of the GMP regulation will not improve the safety and effectiveness of the device. The Hematology Device Classification Panel recommends that isotonic solutions and pH buffers be clasified into class I because these products present no hazard to life, health, or well-being and because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these products.

4. Summary of data on which the recommendation is based: The Pathology Device Classification Panel and the Hematology Device Classification Panel based their recommendations on the Panel members' familiarity and clinical experience with these products, and the products' history of satisfactory performance.

5. Risks to health: Delay in diagnosis: If reagents fail to perform as intended, specimen deterioration, damage, or improper fixation will make the tissue specimen unusable for examination. Additional time will be needed to obtain and prepare a new specimen, thus causing a delay in diagnosis.

Proposed Classification

FDA agrees with the recommendation of the Panels and is proposing that general purpose reagents be classified into class I (general controls). The agency believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these products.

FDA disagrees with the Panels' recommendation that manufacturers of general purpose reagents be exempt from records and reports regulations under section 519 of the act. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device food manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP

requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panels' recommendation that manufacturers of general purpose reagents be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices who does not label or otherwise represent them as sterile be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of general purpose reagents, even when they are not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of general purpose reagents must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of general purpose reagents that are labeled or otherwise represented as sterile is, in the manufacture of these devices, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended by adding new Subpart E including § 864.4010 to read as follows:

Subpart E—Specimen Preparation Reagents

§ 864.4010 General purpose reagent.

(a) *Identification.* A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic histopathology and hematology, and that is not labeled or promoted for medical use or for a specific diagnostic application. General purpose reagents include cytological preservatives, decalcifying reagents, fixatives and adhesives, tissue processing reagents, isotonic solutions, and pH buffers.

(b) *Classification.* Class I (general controls). If the devices are not labeled or otherwise represented as sterile, they are exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-30–5), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27629 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR PART 864]

[Docket No. 78N-1850]

Medical Devices; Classification of Enzyme Preparations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying enzyme preparations into class I (general controls). The FDA is also publishing the recommendations of the Pathology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Pathology Device Classification Panel an FDA advisory committee, made the following recommendation with respect to the classification of enzyme preparations:

1. Identification: Enzyme preparations are products that are used in the histopathology laboratory for the following purposes: (a) to disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin); (b) to disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction); (c) to aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination). The Panel reviewed these products under the name "enzymes."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that enzyme preparations be classified into class I because general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' familiarity and clinical experience with these products, and on

the products' history of satisfactory performance.

5. Risks to health: None specified.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that enzyme preparations be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of these products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart E by adding new § 864.4400 as follows:

§ 864.4400 Enzyme preparations.

(a) *Identification.* Enzyme preparations are products that are used in the histopathology laboratory for the following purposes:

(1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin);

(2) To disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction);

(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27630 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1851]

Medical Devices; Classification of Automated Cell Counters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated cell counters into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of automated cell counters:

1. Identification: An automated cell counter is a device used to count red blood cells, white blood cells, or blood platelets, to measure hemoglobin and hematocrit, and to measure or calculate the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, and the mean corpuscular hemoglobin concentration) using an sample of the patient's peripheral blood (blood circulating in one of the body's extremities, such as the arm).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that automated cell counters be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the information presented by Dr. O. W. Van Assendelft, a consultant to the Panel and the chairman of the Quantitative Cellular Hematology Subcommittee of the National Committee for Clinical Laboratory Standards, who stated that the Subcommittee could develop a standard for automated cell counters in approximately 2 years, and upon the Panel members' own clinical experience with automated cell counters.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of potentially serious disorders such as anemia, leukopenia (a decreased number of leukocytes in the circulating blood), or leukocytosis (an increased number of leukocyes in the circulating blood). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Erroneous cell counts can be potentially life-threatening when those counts are used to monitor patients undergoing chemotherapy.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the automated cell counter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for

this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

The Commissioner has reviewed additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by performance standards. Wintrobe et al. (Ref. *1*) indicate that the results of electronic counters are not necessarily more accurate or more reliable than those of semi-automated or manual cell-counting methods. The authors list 12 sources of error in electronic counters. Williams and Schneider (Ref. *2*) state that errors occur in electronic counting when the white blood cell count is very high. False low white blood cell counts result when significant lymphocytosis (an excess number of lymphocytes in the blood, as in chronic lymphocytic leukemia) is present (Ref. *2*). The Commissioner believes that the matter of error in automated cell counts should be addressed in the device labeling. If the labeling specifies the possible sources of error the operator would be alerted to the possibility of erroneous cell counts under certain operating conditions. A performance standard containing such a labeling requirement would provide a reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Wintrobe, M. M., G. R. Lee, D. R. Boggs, T. C. Bithell, J. W. Athens, and J. Foerster, "Clinical Hematology," Lea and Febiger, Philadelphia, pp. 15–20, 1974.

2. Williams, W. J. and A. S. Schneider, "Examination of the Peripheral Blood," *in* "Hematology," 2d Ed., Edited by W. J. Williams, McGraw-Hill Book Co., New York, pp. 11–14, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart F including new § 864.5200, as follows:

Subpart F—Automated and Semi-Automated Hematology Devices

§ 864.5200 Automated cell counter.

(a) *Identification.* An automated cell counter is a device used to count red blood cells, white blood cells, or blood platelets, to measure hemoglobin and hematocrit, and to measure or calculate the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, and the mean corpuscular hemoglobin concentration) using a sample of the patient's peripheral blood (blood circulating in one of the body's extremities, such as the arm).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27631 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1852]

Medical Devices; Classification of Automated Differential Cell Counters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated differential cell counters into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of automated differential cell counters:

1. Identification: An automated differential cell counter is a device used to identify and classify one or more of the formed elements of the blood.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that automated differential cell counters be classified into class III (premarket approval) because of the possibility of misclassification of cells, which could result in the failure to diagnose a serious disorder. The device therefore presents a potential unreasonable risk of illness or injury. Misclassification by the device could result from a failure to differentiate between cell types or a failure to detect a certain cell type. The Panel was concerned about the fully automated mode of certain differential cell counters. With this type of device, the task of classifying suspect cells, once that of the technician, now is left entirely to the machine. The Panel believes that the ability of this device to accurately identify abnormal cells remains to be established. Therefore, operator verification of the device's abnormal cell identifications is essential. The Panel believes that general controls would not provide

sufficient control over these characteristics. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with automated differential cell counters and on information presented at a symposium entitled "Differential Counters in Hematology" held at the Panel meeting. Among the speakers at the symposium was Dr. Robert Miller of the Johns Hopkins University Medical Center. Dr. Miller discussed difficulties concerning data interpretation, precision and accuracy, correlation to reference methods and error in terms of coincidence, nonreproducible results, nonlinearity, and specific interferences.

5. Risks to health: (a) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the automated differential cell counter be classified into class III (premarket approval). The Commissioner believes that the device is purported or represented for use in the classification of blood cells, a use which is of substantial importance in preventing impairment of human health. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. FDA has reviewed medical literature concerning automated differential cell counters (Refs. *1* through *6*). The medical literature reports two basic methodologies for automated differential cell counting—pattern recognition and flow-through techniques. Pattern recognition systems microscopically scan a fixed, stained blood film. Flow-through systems count and identify cells suspended in a liquid medium.

Pattern recognition systems are handicapped by their lack of accuracy (Ref. *1*). In one study, 68.8 percent of the abnormal cells that the system examined were classified as normal (Ref. *2*). An error of this sort could result in the failure to detect a pathological blood sample (Ref. *1*). Several studies (Refs. *3* through *6*) show a discrepancy between pattern recognition counts and manual counts of monocytes (mononuclear leukocytes). It is suggested that the criteria for identifying monocytes need to be better defined (Refs. *4* and *5*). There also have been reports of discrepancies between pattern recognition counts and manual counts of plasma cells and atypical lymphocytes (Refs. *4* and *6*). The tendency of pattern recognition systems to underestimate the number of atypical lymphocytes is ascribed to flaws in the recognition criteria. Pattern recognition systems also cause difficulty in blood film preparation. Overlapping cells must be avoided, and a uniform distribution of cell types must be achieved (Ref. *1*).

Flow-through systems allow a hundred-fold increase in the rate at which cells are counted. There is imperfect correlation between the classification logic systems of the flow-through machines and the morphological features of the blood cell classes as defined by fixed, Romanowsky-stained preparations (Ref. *1*). Therefore, these machines will fail to classify up to 10 percent of normal cells.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bentley, S. A. and S. M. Lewis, "Automated Differential Leukocyte Counting: The Present State of the Art," *British Journal of Haematology*, 35:481–485, 1977.

2. Megla, G. K., "The LARC Automatic White Blood Cell Analyzer," *Acta Cytologica*, 17:3–14, 1973.

3. Cairns, J. W., et al., "Evaluation of the Hemalog D Differential Leucocyte Counter," *Journal of Clinical Pathology*, 30:997–1004, 1977.

4. Egan, J. J., et al., "Evaluation of an Automated Differential Leukocyte Counting System III. Detection of Abnormal Cells," *American Journal of Clinical Pathology*, 62:537–544, 1974.

5. Christoper, E. A., et al., "Automated Detection of Abnormal Cells," *American Journal of Medical Technology*, 40(1):470–473, 1974.

6. Benzel, J. E., et al., "Evaluation of an Automated Differential Leukocyte Counting System II. Normal Cell Identification," *American Journal of Clinical Pathology*, 62:530–536, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5220 as follows:

§ 864.5220 Automated differential cell counter.

(a) *Identification.* An automated differential cell counter is a device used to identify and classify one or more of the formed elements of the blood.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27632 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1853]

Medical Devices; Classification of Automated Blood Cell Diluting Apparatus

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated blood cell diluting apparatus into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only

the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated blood cell diluting apparatus:

1. Identification: An automated blood cell diluting apparatus is a device used to make, automatically, appropriate dilutions of a blood sample for further quantitative testing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the automated blood cell diluting apparatus be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that labeling of the product be required to include explicit directions for calibration.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with these devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (c) Electrical shock: A malfunction could result in an electric shock.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that automated blood cell diluting apparatus be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner believes that if the operator of this device is properly trained to use this device and employs good laboratory procedures, the risks of hepatitis infection and electrical shock are minimal. Furthermore, if good laboratory practices and quality control procedures are followed, the possibility of improper dilution is minimal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5240 as follows:

§ 864.5240 Automated blood cell diluting apparatus.

(a) *Identification.* An automated blood cell diluting apparatus is a device used to make, automatically, appropriate dilutions of a blood sample for further quantitative testing.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27633 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1854]

Medical Devices; Classification of Automated Cell-Locating Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated cell-locating devices into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated cell-locating devices:

1. Identification: An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a

performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that automated cell-locating devices be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel expressed concern over the potential for bias in the results obtained from the use of these devices due to failure to identify a particular cell type. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with automated cell locating devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated cell-locating devices be classified into class II (performance standards). The differential cell count is used to identify abnormalities that require followup and diagnosis. Leukocytosis (an increase in the number of circulating leukocytes) may be caused by bacterial infection, leukemia, infectious hepatitis and a number of other disorders (Refs. *1* and *2*). Leukopenia (a decreased number of leukocytes in the circulation) may be caused by malaria, viral pneumonia, viral hepatitis, radiation, or drug therapy (Refs. *1* and *2*). Certain disorders cause increased numbers of cells other than leukocytes. The number of platelets in the blood is increased in conditions such as polycythemia vera (a disease state in which the total red cell mass and the total blood volume are increased) and chronic myelogenous leukemia (a leukemia originating in the bone marrow). The Commissioner concurs with the Panel's view that an inaccurate total or differential white cell count resulting from a failure to locate or recognize leukocytes is potentially hazardous to the patient.

The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of this device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), at the address above, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Simmons, A., "Technical Hematology," 2d Ed., J. B. Lippincott Co., Philadelphia, pp. 88 and 109, 1976.

2. Brown, B. A., "Hematology: Principles and Procedures," 2d Ed., Lea and Febiger, Philadelphia, pp. 75–76, 88–89, 100–101, 247, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5260 as follows:

§ 864.5260 Automated cell-locating device.

(a) *Identification.* An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27634 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1855]

Medical Devices; Classification of Red Cell Indices Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying red cell indices devices into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of red cell indices devices:

1. Identification: A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume

(MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias. The Panel considered this generic type of device under the names "red cell indices, calculated" and "red cell indices, measured."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that red cell indices devices be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familiarity with these devices. In making its recommendation, the Panel indicated that because this device is usually a component of a larger system and because the parameters used are often calculated from measurements made by that larger system, the accuracy of the device is dependent upon the accuracy of the larger system. Therefore, performance standards for red cell indices must be developed in conjunction with the performance standards for systems for red cell counting and measurement of the hematocrit and hemoglobin.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of anemia. A miscalculation of the MCV, MCH, and MCHC may lead to an incorrect differential diagnosis between thalassemia minor (a hereditary hemolytic anemia that is the result of decreased synthesis of the beta chains of hemoglobin) and other anemias. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that red cell indices devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necesary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5300 as follows:

§ 864.5300 Red cell indices device.

(a) *Identification.* A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27635 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1856]

Medical Devices; Classification of Microsedimentation Centrifuges

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microsedimentation centrifuges into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of microsedimentation centrifuges:

1. Identification: A microsedimentation centrifuge is a device used to sediment red blood cells for the microsedimentation rate test.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the microsedimentation centrifuge be classified into class I because general

controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' belief that the reference methods for erythrocyte sedimentation rate of the International Committee for Standardization in Hematology (Refs. *1* and *2*) and the National Committee for Clinical Laboratory Standards (Ref. *3*) sufficiently assure the safety and effectiveness of this test. The Panel also considered medical literature concerning the effects of low and high levels of asymmetric macromolecules (Ref. *4*), tube length and diameter (Ref. *5*), disadvantages of the present methodology because of the length of time required to perform the test (Ref. *7*), and the controversy over correction for anemia (Refs. *4* through *7*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of various illnesses, including infections, plasma cell abnormalities, and inflammatory diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the microsedimentation centrifuge be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lewis, S. M., "ICSH Reference Method for the Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Scandinavian Journal of Haematology*, 10:319–320, 1973.

2. Boroviczeny, K. G., et al., "Reference Method for Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Journal of Clinical Pathology*, 26:301–302, 1973.

3. National Committee for Clinical Laboratory Standards: Standard Method for the Human Erythrocyte Sedimentation Rate (ESR) Test, NCCLS Tentative Standard: TSH–1 (proposed 1971, approved 1973), 2525 W. 8th St., Los Angeles, CA 90057.

4. Bull, B. S. and G. Brecher, "An Evaluation of the Relative Merits of the Wintrobe and Westergren Sedimentation Methods, Including Hematocrit Correction," *American Journal of Clinical Pathology*, 62:502–510, 1974.

5. Bull, B. S., "Is a Standard ESR Possible?" *Laboratory Medicine*, 6(11):31–35, 1975.

6. Lascari, A. D., "The Erythrocyte Sedimentation Rate," *Pediatric Clinics of North America*, 19(4):1113–1121, 1972.

7. Raich, P. C. and N. Temperley, "Comparison of the Wintrobe Erythrocyte Sedimentation Rate with the Zeta Sedimentation Ratio," *American Journal of Clinical Pathology*, 65:690–693, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5350 as follows:

§ 864.5350 Microsedimentation centrifuge.

(a) *Identification.* A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27636 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1857]

Medical Devices; Classification of Coagulation Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coagulation instruments into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of coagulation instruments:

1. Identification: A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies. The Panel considered this generic type of device under the names "automated clot timer" and "automated and semiautomated coagulation instrument."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that coagulation instruments be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls

will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familiarity with coagulation instruments. The Panel noted that the Center for Disease Control has proposed studies of automated coagulation instruments and that such studies could aid in the development of a performance standard.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a clotting disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Electrical shock: A malfunction could result in an electric shock.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that coagulation instruments be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that sufficient information exists to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5400 as follows:

§ 864.5400 Coagulation instrument.

(a) *Identification.* A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27637 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1858]

Medical Devices; Classification of Multipurpose Systems for In Vitro Coagulation Studies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multipurpose systems for in vitro coagulation studies into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectivness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of multipurpose systems for in vitro coagulation studies:

1. Identification: A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. This system is used to perform a series of coagulation studies and coagulation factor assays.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this system be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that multipurpose systems for in vitro coagulation studies be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel also expressed concern over the accuracy and precision of the automated systems. Specifically, this concern centered on the ability of the instruments to determine an endpoint in instances of markedly abnormal coagulation. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable asurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familiarity with these systems. The Panel noted that the Center for Disease Control is currently involved in the development of a standardized methodology.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a coagulation disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Electrical shock: A malfunction could result in an electric shock.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that multipurpose systems for in vitro coagulation studies be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5425 as follows:

§ 864.5425 Multipurpose system for in vitro coagulation studies.

(a) *Identification.* A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27638 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1859]

Medical Devices; Classification of Automated Hematocrit Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated hematocrit instruments into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated hematocrit instruments:

1. Identification: An automated hematocrit instrument is a device that measures automatically the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that automated hematocrit instruments be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel stated that the hematocrit is one of the most important determinations in hematology. The Panel stressed the need to standardize the methodology because certain devices claim to measure the packed red cell volume, but in fact measure something else. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the existence of a protocol for the determination of packed red cell volume developed by the World Health Organization and the International Committee for Standardization in Hematology (Ref. *1*). The Panel also considered proficiency testing surveys conducted by the College of American Pathologists and the Center for Disease Control.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hematological abnormality such as anemia, erythrocytosis, or thalassemia (a hereditary hemolytic anemia characterized by a decreased rate of synthesis of one or more of the hemoglobin polypeptide chains). (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the automated hematocrit instrument be classified into class II (performance standards). The Commissioner believes that a

performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Van Assendelft, O. W., J. F. Coster, and P. J. Crossland-Taylor, "Methods for the Determination of Packed Cell Volume," World Health Organization Document Lab/76.3.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5600 as follows:

§ 864.5600 Automated hematocrit instrument.

(a) *Identification.* An automated hematocrit instrument is a device that measures automatically the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27639 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1860]

Medical Devices; Classification of Automated Hemoglobin Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated hemoglobin systems into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated hemoglobin systems:

1. Identification: An automated hemoglobin system is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this product be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that automated hemoglobin systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the fact that a method and reference solution for hemoglobin determination have been addressed in standards developed by the International Committee for Standardization in Hematology (Ref. *1*). This method and reference solution have been accepted by the College of American Pathologists, the American Society of Hematology, and the National Committee for Clinical Laboratory Standards. In addition, a preliminary standard has been devloped by the Center for Disease Control. The Panel also relied upon the medical literature concerning hemoglobinometry. Van Assendelft's discussion (Ref. *2*) of the subject considers the standardization of hemoglobinometry and photometric errors. Van Assendelft, Zijlstra, and van Kampen (Ref. *3*) discuss the sources of error in the cyanmethemoglobin method. They state that errors occur due to improper technique in obtaining and diluting the blood sample. Reagents may have been stored in improper containers, accidentally frozen, or improperly prepared. The hemoglobin determination also may be in error if the measuring instrument was not calibrated and checked with a cyanmethemaglobin reference solution.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The measurement of the patient's hemoglobin is the basis for a decision to intitiate or terminate treatment,

including blood transfusion. (b) Potassium cyanide hazard: The potassium cyanide present in some hemoglobin reagents constitutes a hazard to the laboratory user. (c) Electrical shock: A malfunction could result in an electric shock.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated hemoglobin systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the divice. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Hematology, "Recommendations for Hemogolobinometry in Human Blood," *British Journal of Haematology*, 13 (Supple.):71, 1967.

2. Van Assendelft, O. W., "Spectrophotometry of Hemoglobin Derivatives," Charles C. Thomas Co., Springfield, IL, pp. 35–38, 86–118, 1970.

3. Van Assendelft, O. W., W. G. Zijlstra, and E. J. van Kampen, "Hemoglobinometry: Challenges and Pitfalls," *Proceedings Koninklijke Nederlandse Akademie van Wetenschappen*, 73:104, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5620 as follows:

§ 864.5620 Automated hemoglobin system.

(a) *Identification.* An automated hemoglobin system is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27640 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1861]

Medical Devices; Classification of Automated Heparin Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated heparin analyzers into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated heparin analyzers:

1. Identification: An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient's circulation.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the automated heparin analyzer be classified into class III (premarket approval) because reliance upon the information derived from the use of this device, if inaccurate, could be hazardous to the patient's health. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that there is not sufficient information available regarding the operating principles of this device or the processes involved in its manufacture. The Panel believes that this lack of information would prevent the establishment of a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation, in part, upon the conclusion by the Center for Disease Control that there are insufficient data to determine that the safety and effectiveness of this device could be assured by general controls or a performance standard (Ref. *1*). The Panel also considered Biggs' discussion of heparin neutralization (Ref. *2*), Williams' discussion of heparin and anticoagulant therapy (Ref. *3*), and the

Panel members' clinical experience with heparin neutralization.

5. Risks to health: (a) Hemorrhage or thrombosis: If this device incorrectly reports the level of heparin in the patient's circulation, hemorrhage or thrombosis may result due to the administration of an inappropriate amount of protamine. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated heparin analyzers be classified into class III (premarket approval). This device is intended for use during hemodialysis, to direct heparin therapy, or to monitor heparin levels during surgical procedures such as cardiovascular surgery. If this device fails to report the patient's heparin level accurately during such a procedure, potentially life-threatening thrombosis or hemorrhage could result. Therefore the Commissioner believes that the device presents a potential unreasonable risk of illness or injury (including death) to the patient if the physician directs heparin therapy in reliance upon the information derived from the device. The Commissioner agrees that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Transcript of the Hematology Device Classification Panel Meeting, June 14, 1977, pp. 104–109.

2. Biggs, R., "Human Blood Coagulation, Hemostasis, and Thrombosis," Blackwell Scientific Publications, Oxford, p. 576, 1976.

3. Williams, W. J., "Disorders of Hemostasis—Thrombosis," *in* "Hematology," 2d Ed., Edited by W. J. Williams, McGraw-Hill Book Co., New York, pp. 1481–1489, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5680 as follows:

§ 864.5680 Automated heparin analyzer.

(a) *Identification.* An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient's circulation.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before (*insert date 60 days after date of publication in the* **Federal Register**) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27641 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1862]

Medical Devices; Classification of Automated Platelet Aggregation Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated platelet aggregation systems into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated platelet aggregation systems:

1. Identification: An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that automated platelet aggregation systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel expressed concern over the variation in results obtained with these systems. The Panel ascribed this variation to the nonuniform stability and reactivity of the reagents. The Panel recommends that the labeling be required to describe the stability of the reagents and their active constituents, and directions for storage. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance

standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and knowledge of the medical literature concerning platelet aggregation. The Panel considered a review article by Arkel (Ref. *1*) describing platelet aggregation and its clinical applications. Arkel states that although inherited platelet function disorders are rare, they are dangerous because they can cause excessive bleeding during surgery. Han and Ardlie (Ref. *2*) describes the effects of pH, temperature, and calcium concentration on platelet aggregation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a platelet disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Failure to diagnose a platelet disorder could result in bleeding during surgery.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated platelet aggregation systems be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Arkel, Y. W., "Evaluation of Platelet Aggregation in Disorders of Hemostasis," *Medical Clinics of North America*, 60(5):881–911, 1976.

2. Han, P. and N. G. Ardlie, "The Influence of pH, Temperature, and Calcium on Platelet Aggregation: Maintenance of Environmental pH and Platelet Function for In Vitro Studies in Plasma Stored at 37° C," *British Journal of Haematology*, 26:373–389, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5700 as follows:

§ 864.5700 Automated platelet aggregation system.

(a) *Identification.* An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27642 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1863]

Medical Devices; Classification of Automated Sedimentation Rate Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated sedimentation rate devices into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classfication of automated sedimentation rate devices:

1. Identification: An automated sedimentation rate device is an instrument that measures automatically the erythrocyte sedimentation rate in whole blood. Because an increased sedimentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the automated sedimentation rate device be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' belief that the reference method for erythrocyte sedimentation rate (Refs. *1* and *2*) of the International Committee for Standardization in Hematology and the reference method of the National Committee for Clinical Laboratory Standards sufficiently control the safety and effectiveness of this test. The Panel also considered medical literature concerning the effect of low and high levels of asymmetric macromolecules (Ref. *4*), tube length and diameter (Ref. *5*), disadvantages of the

present methodology because of the length of time required to perform the test (Ref. *7*), and the controversy over correction for anemia (Refs. *4* through *7*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of various illnesses, including infections, plasma cell abnormalities, and inflammatory diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated sedimentation rate devices be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lewis, S. M., "ICSH Reference Method for the Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Scandinavian Journal of Hematology*, 10:319–320, 1973.

2. Boroviczeny, K. G., et al., "Reference Method for the Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Journal of Clinical Pathology*, 26:301–302, 1973.

3. National Committee for Clinical Laboratory Standards: Standard Method for the Human Erythrocyte Sedimentation Rate (EST) Test NCCLS Tentative Standard: TSH–1 (proposed 1971, approved 1973), 2525 W. 8th St., Los Angeles, CA 90057.

4. Bull, B. S. and G. Brecher, "An Evaluation of the Relative Merits of the Wintrobe and Westergren Sedimentation Methods, Including Hematocrit Correction," *American Journal of Clinical Pathology*, 62:502–510, 1974.

5. Bull, B. S., "Is a Standard ESR Possible?" *Laboratory Medicine*, 6(11):31–35, 1975.

6. Lascari, A. D., "The Erythrocyte Sedimentation Rate," *Pediatric Clinics of North America*, 19(4):1113–1121, 1972.

7. Raich, P. C. and N. Temperley, "Comparison of the Wintrobe Erythrocyte Sedimentation Rate with the Zeta Sedimentation Ratio," *American Journal of Clinical Pathology*, 65:690–693, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5800 as follows:

§ 864.5800 Automated sedimentation rate device.

(a) *Identification.* An automated sedimentation rate device is an instrument that measures automatically the erythrocyte sedimentation rate in whole blood. Because an increased sedimentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27643 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1864]

Medical Devices; Classification of Automated Slide Spinners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated slide spinners into class I (general controls). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated slide spinners:

1. Identification: An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body's extremities, such as the arm).

2. Recommended classification: Class II (general controls). The Panel recommends that there be no exemptions.

3. Summary the reasons for recommendation: The Panel recommends that the automated slide spinner be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with this device.

5. Risks to health: (a) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (b) Electrical shock: A malfunction could result in electric shock. (c) Cuts and abrasions: There is a risk of injury to the operator from borken glass microscope slides if the device fails to function properly. (d) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a serious disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. There is a risk of misdiagnosis due to mislabeling of slides and poor quality of spun slide preparations.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that automated slide spinners be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Commissioner believes that if the operator is properly trained to use this device and follows the manufacturer's instructions carefully, the risks of hepatitis, injury from broken glass, mislabeling of slides, and poor slide quality are minimal. If good laboratory practices and quality control procedures are followed, the possibility of hepatitis infection or mislabeling of slides is minimal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5850 as follows:

§ 864.5850 Automated slide spinner.

(a) *Identification.* An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body's extremities, such as the arm).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, (*insert date 60 days after date of publication in the* **Federal Register**) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27644 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1865]

Medical Devices; Classification of Blood Volume Measuring Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood volume measuring devices into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of blood volume measuring devices:

1. Identification: A blood volume measuring device is a manual semiautomated, or automated system that is used to calculate the red cell mass, plasma volume, and total blood volume.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the blood volume measuring device be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with these systems.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of polycythemia vera (a disease characterized by an absolute increase in the red cell mass and the total blood volume). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendations and is proposing that blood volume measuring devices be classified into class II (performance standards).

An FDA review of the medical literature shows that certain aspects of blood volume measuring devices could be addressed in a performance standard. The use of labeled red cells is the method of choice for measuring the total circulating red cell volume. Use of either stable or radioactive carbon monoxide as a label results in a tendency to overestimate the total red cell volume (Ref. *1*). There also are inherent difficulties in measurement of plasma volume. Allowance must be made for the time required for the label to mix with the plasma and the continual elimination of the label from the plasma. The plasma volume does not remain constant and therefore is hard to define (Ref. *1*). If the Evans blue dye method is employed, it is difficult to obtain an accurate measurement. The deep blue dye hampers any measurement made in a syringe. The

patient also must be fasting to control the opacity of the plasma (Ref. *2*). There are also instances in which the peripheral blood volume does not correlate closely with the red cell volume (Ref. *2*).

In addition to the uses cited by the Panel, the blood volume measurement is used in the following situations: to evaluate blood and fluid losses during major surgical procedures and following trauma (e.g., burns), to serve as a guide in preoperative and postoperative transfusion therapy, to evaluate gastrointestinal and uterine bleeding, and to aid in the diagnosis of hypovolemic shock (i.e., shock characterized by abnormally low levels of fluid in the body's circulatory system). An inaccurate blood volume measurement in these circumstances poses great potential for harm. The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that sufficient information exists to establish a performance standard for the device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Berlin, N. I., "Laboratory Evaluation of Erythrokinetics," *in* "Hematology," 2d Ed., Edited by W. J. Williams, McGraw-Hill Book Co., New York, pp. 237–240, 1977.

2. Simmons, A., "Technical Hematology," 2d Ed., J. B. Lippincott Co., Philadelphia, pp. 338–339, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart F by adding new § 864.5950 as follows:

§ 864.5950 Blood volume measuring device.

(a) *Identification.* A blood volume measuring device is a manual, semiautomated, or automated system that is used to calculate the red cell mass, plasma volume, and total blood volume.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27645 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1866]

Medical Devices; Classification of Bleeding Time Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bleeding time devices into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bleeding time devices:

1. Identification: A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patient's skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bleeding time devices be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that it is vitally important that the template used to make the incision be sterilizable or disposable. If the template is sterilizable, the label should specify the method of sterilization to be used. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' knowledge of, and clinical experience with, this device. In making its recommendation, the Panel indicated that a standard should not be difficult to develop because the current template, with its well-standardized design, works well and is widely accepted.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a potentially serious bleeding disorder.

Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The result could be severe bleeding during surgery. (b) Scarring: If the device is used improperly the patient may receive a permanent scar. (c) Cuts and abrasions: The spring-loaded blades may injure the technician if the device is not handled properly. (d) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that bleeding time devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commission also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart G including new § 864.6100 as follows:

Subpart G—Manual Hematology Devices

§ 864.6100 Bleeding time device.

(a) *Identification.* A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patients's skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27846 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1867]

Medical Devices; Classification of Capillary Blood Collection Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying capillary blood collection tubes into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of capillary blood collection tubes:

1. Identification: A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that capillary blood collection tubes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with the device.

5. Risks to health: None identified.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that capillary blood collection tubes be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6150 as follows:

§ 864.6150 Capillary blood collection tube.

(a) *Identification.* A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27647 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1868]

Medical Devices; Classification of Manual Blood Cell Counting Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual blood cell counting devices into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual blood cell counting devices:

1. Identification: A manual blood cell counting device is a device used to count red blood cells, white blood cells, and blood platelets. The Panel considered this generic type of device under the names "hemocytometer," "differential hand tally," "quantitative hematology pipettes," and "manual platelet counting."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that manual blood cell counting devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with these devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that manual blood cell counting devices be classified into class I (general controls), with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner believes that if the blood cells are counted according to an established procedure, the chance of an inaccurate cell count is greatly reduced.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner, it is proposed that Part 864 be amended in Subpart G by adding new § 864.6160, to read as follows:

§ 864.6160 Manual blood cell counting device.

(a) *Identification.* A manual blood cell counting device is a device used to count red blood cells, white blood cells, and blood platelets.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27648 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1869]

Medical Devices; Classification of Hematocrit Measuring Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hematocrit measuring devices into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification

Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hematocrit measuring devices:

1. Identification: A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in blood to determine whether the patient's total red cell volume is normal or abnormal. Abnormal states include anemia (an abnormally low total red cell volume) and erythrocytosis (an abnormally high total red cell mass). The packed red cell volume is produced by centrifuging a given volume of blood. The Panel considered this generic type of device under the names "hematocrit, centrifugal force packed, cell volume" and "hematocrit tubes, racks, sealer, and holder."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hematocrit measuring devices be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel indicated that measurement of the hematocrit is one of the most important measurements in hematology. The Panel stressed the need to standardize the methodology because of the use of this measurement to distinguish various hematogical abnormalities and because certain devices claim to measure the packed red cell volume, but in fact measure something else. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the existence of a protocol for the determination of packed red cell volume developed by the World Health Organization and the International Committee for Standardization in Hematology (Ref. *1*). The Panel also considered proficiency testing surveys conducted by the College of American Pathologists and the Center for Disease Control.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hematological abnormality such as anemia, erythrocytosis, or thalassemia (a hereditary hemolytic anemia characterized by a decreased rate of synthesis of one or more of the hemoglobin chains). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Hepatitis infection. Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the hematocrit measuring devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Van Assendelft, O. W., J. F. Coster, and P. J. Crossland-Taylor, "Methods for the Determination of Packed Cell Volume," World Health Organization Document LAB/76.3.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6400 as follows:

§ 864.6400 Hematocrit measuring device.

(a) *Identification.* A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in blood to determine whether the patient's total red cell volume is normal or abnormal. Abnormal states include anemia (an abnormally low total red cell volume) and erythrocytosis (an abnormally high total red cell mass). The packed red cell volume is produced by centrifuging a given volume of blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27649 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1870]

Medical Devices; Classification of Iron Kinetics Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying iron kinetics tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and

Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierkscheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of iron kinetics tests:

1. Identification: An iron kinetics test is a device used to determine the plasma iron clearance and red cell iron incorporation. The information obtained from this system is used to diagnose iron metabolism disorders.

2. Recommended Classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that iron kinetics tests be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with this device.

5. Risks to health: (a) Radiation hazard: The user may be exposed to radiation from radioisotopes that are a part of this device. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of an iron metabolism disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that iron kinetics tests be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6475 as follows:

§ 864.6475 Iron kinetics test.

(a) *Identification.* An iron kinetics test is a device used to determine the plasma iron clearance and red cell iron incorporation. The information obtained from this system is used to diagnose iron metabolism disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27650 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1871]

Medical Devices; Classification of Occult Blood Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying occult blood tests into class II (performance standards). The FDA is also publishing the recommendations of two FDA advisory committees concerning this device. The Hematology Device Classification Panel recommends that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The Clinical Chemistry Device Classification Panel recommends that this device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Clinical Chemistry Device Classification Panel, two FDA advisory committees, made the following recommendations with respect to the classification of occult blood tests:

1. Identification: An occult blood test is a device used to detect occult blood in urine or feces. (Occult blood is blood present in such small quantities that it can be detected only by chemical tests of suspected material, or by microscopic or spectroscopic examination.) The Panels considered this generic type of device under the names "occult blood reagent," "colorimetric, occult blood in

urine," and "enzymatic method, occult blood in urine."

2. Recommended classification: The Hematology Device Classification Panel recommends that the occult blood reagent be classified into class I (general controls) with no exemptions. The Clinical Chemistry Device Classification Panel recommends that colorimetric and enzymatic methods for the detection of occult blood in urine be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that occult blood tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The Clinical Chemistry Device Classification Panel recommends that the occult blood test be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data upon which the recommendation is based: The Panels based their recommendations upon the Panel members' clinical experience with occult blood tests, the results of interlaboratory proficiency studies, and Derman and Pauker's article on the various methodologies for detecting occult blood (Ref. *1*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of gastro-intestinal bleeding, renal disease, urinary tract disease, or hemoglobinuria (hemoglobin in the urine). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner has reviewed the Panels' recommendations and is proposing that occult blood tests be classified into class II (performance standards). The Commissioner has reviewed additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by performance standards. Adlercreutz, Liewendahl, and Virkola have compared the various tests for the detection of occult blood in the feces (Ref. *2*). They note features of the test that need to be improved or standardized: sensitivity, identification of the amount of feces to be used, and measures to prevent contamination of the surrounding area.

The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. The Commissioner believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Derman, H. and S. Pauker, "Detection of Occult Blood in Feces and Urine," in "Hemoglobin, Its Precursors and Metabolites," Edited by F. W. Sunderman and F. W. Sunderman, Jr., J. P. Lippincott Co., Philadelphia, pp. 70–80, 1964.

2. Adlercreutz, H., K. Liewendahl, and P. Virkola, "Evaluation of Fecatest, a New Guaiac Test for Occult Blood in Feces," *Clinical Chemistry*, 24(5):756–761, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6550 as follows:

§ 864.6550 Occult blood test.

(a) *Identification.* An occult blood test is a device used to detect occult blood in urine or feces. (Occult blood is blood present in such small quantities that it can be detected only by chemical tests of suspected material, or by microscopic or spectroscopic examination.)

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27651 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1872]

Medical Devices; Classification of the Osmotic Fragility Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying osmotic fragility tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides

background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of the osmotic fragility tests:

1. Identification: An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that osmotic fragility tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel stated that it is customary to run samples of normal blood as controls; and if this is done, there is little chance of an erroneous result.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familiarity with these tests: In certain hemolytic anemias, e.g., hereditary spherocytosis (a congenital, familial form of hemolytic anemia) and acquired hemolytic anemia (anemia caused by nonhereditary factors such as infectious agents, poisons, and physical agents), the resistance of the red cells to hemolysis by hypotonic solutions is reduced. Conversely, resistance is increased in thalassemia (another type of hereditary hemolytic anemia), sickle cell anemia, and ordinary hypochromic (iron deficiency) anemia.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hereditary spherocytosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The patient could be subjected to a splenectomy unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that osmotic fragility tests be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner believes that if the volumes of blood and saline are measured precisely, if the dilutions are performed carefully, if the proper pH and temperature are maintained, and if samples of normal blood are run as controls, this test can be carried out accurately.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6600 as follows:

§ 864.6600 Osmotic fragility test.

(a) *Identification.* An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docke number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27652 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1873]

Medical Devices; Classification of Platelet Adhesion Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying platelet adhesion tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of platelet adhesion tests:

1. Identification: A platelet adhesion test is a device used to determine in vitro platelet function.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that platelet adhesion tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that reliance upon diagnostic information derived from the use of this device, if inaccurate, could be hazardous to the patient's health. The Panel recommended that this device not be used to predict thrombotic tendency.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience which indicates that the required rate of blood flow through a glass bead column has been established. The Panel also based its recommendation upon the medical literature concerning this device. Bowie and Owen (Ref. *1*) have found this test to be especially useful in evaluating and confirming a diagnosis of von Willebrand's disease (a bleeding

disorder characterized by a prolonged bleeding time and decreased levels of factor VIII, an antihemophilic factor). A platelet adhesion test, when used in combination with the bleeding time, can detect the presence of platelet defects, but a platelet aggregation study must be done to determine the nature of the defect (Ref. *2*). Other studies (Refs. *3* and *4*) have investigated the effects of glass surfaces, platelet aggregation, adenine diphosphate, fibrinogen, and calcium on platelet adhesion.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of von Willebrand's disease, a thrombopathy (a blood coagulation disorder due to platelet dysfunction), a platelet defect, or deficiencies of blood coagulation factor VIII or factor IX (plasma thromboplastin component). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that platelet adhesion tests be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bowie, E. J. W. and C. A. Owen, Jr., "The Value of Measuring Platelet Adhesiveness in the Diagnosis of Bleeding Diseases," *American Journal of Clinical Pathology*, 60:302–308, 1973.

2. Papayannis, A. G. and M. C. G. Israels, "The Value of the Platelet Adhesiveness Test in the Assessment of Abnormalities of Platelet Function," *Acta Hematologica*, 46:1–13, 1971.

3. Rossi, E. C. and D. Green, "A Study of Platelet Retention by Glass Beed Columns ('Platelet Adhesiveness' in Normal Subjects)," *British Journal of Haematology*, 23:47–57, 1972.

4. George, J. N., "Direct Assessment of Platelet Adhesion to Glass: A Study of the Forces of Interaction and Effects of Plasma and Serum Factors, Platelet Function and Modification of the Glass Surface," *Blood*, 40:862–874, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6650 as follows:

§ 864.6650 Platelet adhesion test.

(a) *Identification.* A platelet adhesion test is a device used to determine in vitro platelet function.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27653 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1874]

Medical Devices; Classification of Platelet Aggregometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying platelet aggregometers into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health , Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A notice elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of platelet aggregometers:

1. Identification: A platelet aggregometer is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that platelet aggregometers be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient countrol over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and knowledge of the medical literature concerning platelet aggregation. The Panel considered a review article by Arkel (Ref. *1*) describing platelet aggregation and the evaluation of platelet function in hemostasis and thrombosis. Arkel indicates that although inherited platelet function

disorders occur infrequently, they can cause bleeding problems during surgery. Han Ardlie (Ref. *2*) described the effects of pH, temperature, and calcium concentration on platelet aggregation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a platelet disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Bleeding from an undetected platelet disorder could result in complications during surgery.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the platelet aggregometer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Arkel, Y. S., "Evaluation of Platelet Aggregation in Disorders of Hemostasis," *Medical Clinics of North America*, 60(5):881–911, 1976.

2. Han, P. and Ardlie, N. G., "The Influence of pH, Temperature, and Calcuim on Platelet Aggregation: Maintenance of Environmental pH and Platelet Function for in Vitro Studies in Plasma," *British Journal of Haematology*, 26:373–389, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 864 in Subpart G by adding new § 864.6675 as follows:

§ 864.6675 Platelet aggregometer.

(a) *Identification.* A platelet aggregometer is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk document found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc 79–27664 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1875]

Medical Devices; Classification of the Red Cell Survival Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the red cell survival tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of the red cell survival tests:

1. Identification: A red cell survival test is a device system used to measure the mean red cell survival or loss in either a patient or a suitable recipient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that red cell survival tests be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnositic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the existence of a red cell survival methodology recommended by the International Committee for Standardization in Hematology (Ref. *1*) and upon the Panel member's clinical experience and familiarity with these tests.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a red blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products or blood aerosols presents a risk of hepatitis infection. (c) Radiation hazard: The user may be exposed to radiation from radioisotopes that are a part of this device.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the red cell survival test be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. ICSH panel on Diagnostic Applications of Radioisotopes in Haematology, "ICSH Recommended Method for Radioisotope Red Cell Survival Studies," *British Journal of Haematology*, 21(2):241–250, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6750 as follows:

§ 864.6750 Red cell survival test.

(a) *Identification.* A red cell survival test is a device system used to measure the mean red cell survival or loss in either a patient or a suitable recipient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27655 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1876]

Medical Devices; Classification of Erythrocyte Sedimentation Rate Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying erythrocyte sedimentation rate tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of erythrocyte sedimentation rate tests:

1. Identification: An erythrocyte sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance. An increased rate indicates tissue damage or inflammation. The Panel considered this generic type of device under the names "erythrocyte sedimentation rate" and "sedimentation rate tubes."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that erythrocyte sedimentation rate tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the belief that the erythrocyte sedimentation rate reference methods of the International Committee for Standardization in Hematology (Refs. *1* and *2*) and the National Committee for Clinical Laboratory Standards (Ref. *3*) sufficiently control the safety and effectiveness of this test. The Panel also considered medical literature concerning the effects of low and high levels of asymmetric macromolecules (Ref. *4*), tube length and diameter (Ref. *5*), disadvantages of present methodology because of the length of time required to perform the test (Ref. *7*), and the controversy over correction for anemia (Refs. *4* through *7*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of various illnesses, including infections, plasma cell abnormalities, and inflammatory diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that erythrocyte sedimentation rate tests be classified into class I (general controls) with no exemptions. The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The medical literature concerning the erythrocyte sedimentation rate test describes it as a nonspecific test that can indicate tissue damage or inflammation (Refs. *5, 6, 8,* and *9*). Therefore, the erythrocyte sedimentation rate is of value in screening for infection and in following the progress of a disease. Because this test is used to confirm a diagnosis based on another test, the risk of misdiagnosis due solely to the erythrocyte sedimentation rate is small (Ref. *6*).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Hematology, "ICSH Reference Method for the Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Scandinavian Journal of Hematology*, 10:319–320, 1973.

2. Boroviczeny, K. G. et al., "Reference Method for the Erythrocyte Sedimentation Rate (ESR) Test on Human Blood," *Journal of Clinical Pathology*, 28:301–302, 1973.

3. National Committee for Clinical Laboratory Standards: Proposed Standard Method for the Human Erythrocyte Sedimentation Rate (ESR) Test, NCCLS Tentative Standard TSH–1 (Proposed 1971, approved 1973), 2525 W. 8th St., Los Angeles, CA 90057.

4. Bull, B. S. and G. Brecher, "An Evaluation of the Relative Merits of the Wintrobe and Westergren Sedimentation Methods, Including Hematocrit Correction," *American Journal of Clinical Pathology*, 62:502–510, 1974.

5. Bull, B. S., "Is a Standard ESR Possible?" *Laboratory Medicine*, 6(11):31–35, 1975.

6. Lascari, A. D., "The Erythrocyte Sedimentation Rate," *Pediatric Clinics of North America*, 19(4):1113–1121, 1972.

7. Raich, P. C. and N. Temperly, "Comparison of the Wintrobe Erythrocyte Sedimentation Rate with the Zeta Sedimentation Ratio," *American Journal of Clinical Pathology*, 65:690–693, 1976.

8. Simmons, A., "Technical Hematology," 2d Ed., J. B. Lippincott Co., Philadelphia, pp. 326–329, 1976.

9. Brown, B. A., "Hematology: Principles and Procedures," 2d Ed., Lea and Febiger, Philadelphia, pp. 93–94, 1976

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart G by adding new § 864.6700 as follows:

§ 864.6700 Erythrocyte sedimentation rate test.

(a) *Identification.* An erythroctye sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance. An increased rate indicates tissue damage or inflammation.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27656 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1877]

Medical Devices; Classification of Adenine Nucleotide Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying adenine nucleotide assays into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of adenine nucleotide assays:

1. Identification: An adenine nucleotide assay is a device that measures the levels in the body tissues and fluids of adenine nucleotide (a compound consisting of the base adenine, a sugar, and a phosphate group). This measurement is often made with a photometer (a device that measures light intensity). Adenosine diphosphate (ADP) is the nucleotide responsible for platelet aggregation in the arrest of bleeding.

2. Recommended classification: Class I (general controls): The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that adenine nucleotide assays be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with adenine nucleotide assays.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a serious disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (c) Electrical shock: A malfunction in the electrical system of the photometer could result in an electrical shock.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that adenine nucleotide assays be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that, if users heed warnings in the labeling against use of contaminated or deteriorating reagents, the enzyme preparation will be pure and stable. If the user employs good laboratory procedures for handling blood, the risk of hepatitis should be minimal. If the operating instructions for the photometer are followed carefully, the risk of electrical shock will also be minimal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended by adding

Subpart H including new § 864.7040, as follows:

Subpart H—Hematology Kits and Packages

§ 864.7040 Adenine nucleotide assay.

(a) *Identification.* An adenine nucleotide assay is a device that measures the levels in the body tissues and fluids of adenine nucleotide (a compound consisting of the base adenine, a sugar, and a phosphate group). This measurement is often made with a photometer (a device that measures light intensity). Adenosine diphosphate (ADP) is the nucleotide responsible for platelet aggregation in the arrest of bleeding.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27657 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1878]

Medical Devices; Classification of Antithrombin III Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antithrombin III asssays into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel and the Immunology Device Classification Panel that this device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of antithrombin III assays:

1. Identification: An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance that acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

2. Recommended classification: The Hematology Device Classification Panel recommends that antithrombin III assays be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Immunology Device Classification Panel recommends that antithrombin III assays be classified into class II and that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that antithrombin III assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel also expressed concern about the substances and conditions that can cause a falsely elevated antithrombin III determination. The Immunology Device Classification Panel recommends that the device be classified into class II to assure the product's reliability by means of adequate controls over the sensitivity, specificity, and stability of the reagents used in the device. Lack of sensitivity, specificity, or stability may cause a product malfunction, resulting in an erroneous diagnosis of a hypercoagulation state (a state characterized by increased susceptibility to coagulation) and in subsequent patient mismanagement. Information concerning the concentration of antithrombin III is of great clinical significance in determining the likelihood of clot formation, particularly when the concentration falls to 50 percent of normal or lower. Patients who have developed thrombosis, emboli, or disseminated intravascular coagulation have abnormally low levels of antithrombin III. The level of this substance is also low in patients with congenital antithrombin III deficiency, liver diseases such as cirrhosis and hepatitis, or diabetes mellitus, and in patients who are taking oral contraceptives. Increased antithrombin III levels are associated with the use of anticoagulants, congenital heart diseases, hemophilia, and other blood disorders. Both Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Hematology Device Classification Panel based its recommendation on the Panel members' clinical experience with this device, which indicates that this is a relatively simple assay. The Immunology Device Classification Panel based its recommendation upon the Panel members' clinical experience with this device and upon a review of the medical literature (Refs. *1* through *4*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a

hypercoagulation state resulting from an antithrombin III deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Inappropriate heparin therapy, such as the administration of anticoagulants or factor IX concentrates to hemophiliacs, could result.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that antithrombin III assays be classified into class II (performance standards). An FDA review of medical literature concerning antithrombin III revealed a considerable body of evidence to support the recommendations of both Panels (Refs. *5* through *10*).

Assays of antithrombin III may be divided into three types: Clotting assays based upon the neutralization of thrombin or factor Xa in the absence of heparin, clotting assays in the presence of added heparin, and immunoassays (Ref. *5*). Clotting assays of both types tend to be nonspecific, time consuming, unwieldy, and characterized by poor reproducibility (Refs. *6*, *7*, and *8*). The addition of heparin increases the assay's specificity by shortening its incubation period, but may require the use of a heparin-neutralizing agent (Refs. *5*, *6*, and *9*). Regardless of whether heparin is added, clotting assays are affected to a minor degree by the presence of alpha 2 macroglobulin. (A high molecular weight protein found in the blood in many diseases, alpha 2 macroglobulin inhibits clotting by binding irreversibly to the enzyme thrombin (Ref. *5*).) Because antithrombin III inhibits serine proteases (enzymes that break down protein) by forming an irreversible one-to-one complex via the active center serine of the enzyme, it is important to choose the proper serine protease to incubate with the antithrombin III. Although the usual choice is either thrombin or coagulation factor Xa (activated Stuart factor), other enzymes such as plasmin or trypsin are sometimes employed (Ref. *9*). If thrombin is used, the amount of antithrombin III that is measured depends upon the concentration of purified thrombin (Refs. *8* and *9*) and upon the complete, rapid, and irreversible inactivation of the thrombin by antithrombin III. The amount of antithrombin III that is measured also depends upon the method of defibrination used (Ref. *8*), although at least one assay requires no defibrination (Ref. *6*). The selection of the correct substrate is also important (Ref. *9*). Some methods recommend a chromogenic substrate (Ref. *6*). Immunoassays are generally lengthy (Ref. *5*). With these assays, an inactive protein often produces a positive result (Ref. *10*). Although immunoassays seem to be the method of choice for screening large numbers of patients, it has not been proven that immunoassays accurately measure antithrombin III in all disease states (Ref. *3*).

Oral contraceptives increase the production of thrombin while inhibiting antithrombin III activity. This situation can lead to thrombotic complications (Ref. *8*).

FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A Performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bick, R. L., I. Kovacs, and L. F. Fekete, "A New Two-Stage Functional Assay for Antithrombin III (Heparin Cofactor). Clinical and Laboratory Evaluation," *Thrombosis Research*, 8:745–756, 1976.

2. Fagerhol, M. D. and U. Abildgaard, "Immunological Studies on Human Antithrombin III. Influence of Age, Sex, and Use of Oral Contraceptives," *Scandinavian Journal of Haematology*, 7:10–17, 1970.

3. Von Kaulla, E. and K. M. von Kaulla, "Deficiency of Antithrombin III Activity with Hereditary Thrombosis Tendency," *Journal of Medicine*, 3:349–358, 1972.

4. Yue, R. H., T. Starr, and M. M. Gertler, "Quantitative Determination of Total Antithrombin III in Plasma," *Thrombosis et Diathesis Haemorrhagica*, 30:84–92, 1973.

5. Gitel, S. N., and S. Wessler, "Plasma Antithrombin III: A Quantiative Assay of Biological Activity," *Thrombosis Research*, 7:5–16, 1975.

6. Odegard, O. R., M. Lie, and U. Abildgaard, "Heparin Cofactor Activity Measured with an Amidolytic Method," *Thrombosis Research*, 6:287–294, 1975.

7. Miale, J. B., "Laboratory Medicine Hematology," C. V. Moseby Co., St. Louis, pp. 1083–1085, 1977.

8. Howie, P. W., C. R. M. Prentice, and G. P. McNicol, " A Method of Antithrombin Estimation Using Plasma Defibrinated with Ancrod," *British Journal of Haematology*, 25:101–110, 1973.

9. Damus, P. S. and R. D. Rosenberg, "Antithrombin-Heparin Cofactor," *Methods in Enzymology*, 45:653–669, 1977.

10. Rosenberg, R. D. and P. S. Damus, "The Purification and Mechanism of Action of Human Antithrombin-Heparin Cofactor," *Journal of Biological Chemistry*, 248:6490–6505, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7060 as follows:

§ 864.7060 Antithrombin III assay.

(a) *Identification.* An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27658 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1879]

Medical Devices; Classification of Cell Enzyme Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cell enzyme assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the

safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cell enzyme assays:

1. Identification: A cell enzyme assay is a device used to measure the activity in red cells, white cells, or both, of various clinically important enzymes and metabolites, such as pyruvate kinase and 2,3-diphosphoglycerate. A red cell enzyme assay is used to determine the enzyme defects responsible for a patient's hereditary hemolytic anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that cell enzyme assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that the kits currently being marketed are not sufficiently reliable to accurately diagnose a heterozygous enzyme deficiency state, and the Panel recommended that these products be so labeled.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familiarity with the commercially available products and upon the existence of a standard for red cell enzymes developed by the International Committee for Standardization in Hematology (Ref. *1*). Two Panel members, T. F. Necheles, M.D., Ph.D., and H. Frischer, M.D., described numerous instances in which patients were to have had their spleen removed because the device failed to detect a pyruvate kinase deficiency. These device failures resulted in misdiagnoses of hereditary spherocytosis (a congenital hemolytic anemia).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a serious disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Such therapy may include inappropriate drug therapy, contraindicated splenectomy, or unnecessary transfusions.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that cell enzyme assays be classified into class II (performance standards). An FDA review of the medical literature concerning the determination of various red and white cell enzymes found evidence to support the Panel recommendation (Refs. *2* and *3*). One article stated that the crucial factor in the diagnosis of an enzyme deficiency is the demonstration of that deficiency by enzyme assay (Ref. *2*).

FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Beutler, E., et al., "International Committee for Standardization in Haematology: Recommended Methods for Red Cell Enzyme Analysis," *British Journal of Haematology*, 35(2):331–340, 1977.

2. Valentine, W. N., "Deficiency of Other Enzymes Leading to Anemia," *in* "Hematology," 2d Ed., Edited by W. J. Williams, McGraw-Hill Book Co., New York, pp. 483–486, 1977.

3. Miale, J. B., "Laboratory Medicine Hematology," C. V. Moseby Co., St. Louis, p. 1024, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7100 as follows:

§ 864.7100 Cell enzyme assay.

(a) *Identification.* A cell enzyme assay is a device used to measure the activity in red cells, white cells, or both, of various clinically important enzymes and metabolites, such as pyruvate kinase and 2,3-diphosphoglycerate. A red cell enzyme assay is used to determine the enzyme defects responsible for a patient's hereditary hemolytic anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27659 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N-1880]

Medical Devices; Classification of Activated Whole Blood Clotting Time Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying activated whole blood clotting time tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of activated whole blood clotting time tests:

1. Identification: An activated whole blood clotting time test is a device used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism, and therapy for deficiencies of coagulation factors VIII (antihemophilic factor), IX (plasma thromboplastin component), and XI (plasma thromboplastin antecedent), by measuring the coagulation time of whole blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that activated whole blood clotting time tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that the product labeling be required to warn the user that this product should not be used as a screening test for coagulation defects.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with the device and upon an article by Hattersley (Ref. *1*) that stated that the activated whole blood clotting time test is a well-established means of monitoring heparin therapy and therapy for deficiencies of coagulation factors VIII, IX, and XI.

5. Risks to health: Hemorrhage or thrombosis: If the device does not accurately report the level of heparin in the patient's blood and the physician prescribes an inappropriate dosage of protamine (a heparin neutralizing drug), hemorrhage or thrombosis may result.

Proposed Classification

The FDA agrees with the Panel's recommendation and is proposing that activated whole blood clotting time tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hattersley, P. G., "Progress Report: The Activated Coagulation Time of Whole Blood (ACT)," *American Journal of Clinical Pathology*, 66(5):899-904, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7140 as follows:

§ 864.7140 Activated whole blood clotting time test.

(a) *Identification.* An activated whole blood clotting time test is a device used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism, and therapy for deficiencies of coagulation factors VII (antihemophilic factor), IX (plasma thromboplastin component), and XI (plasma thromboplastin antecedent), by measuring the coagulation time of whole blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27660 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1881]

Medical Devices; Classification of Erythropoietin Assays

AGENCY: Food and Drug Adminstration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying erythropoietin assays into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of erythropoietin assays:

1. Identification: An erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.

2. Recommended classification: Class III (premarket approval). The Panel recommends that establishing premarket approval for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that erythropoietin assays be classified into class III because the device is purported or represented to be for use in the diagnosis of polycythemia vera, a potentially fatal disease characterized by erythrocytosis (increased total blood volume) and often accompanied by increased leukocyte and platelet counts. This use presents a potential unreasonable risk of illness or injury if the diagnosis is missed due to inaccurate diagnostic information derived from the use of this assay. The Panel believes that this assay is suitable only for research purposes because it lacks sufficient accuracy, precision, sensitivity, and specificity for clinical use. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that insufficient information exists to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The device therefore should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance and thus assure its safety and effectiveness. On two separate occasions the Panel discussed the possibility of banning this device. One Panel meeting included discussion of a draft of a National Committee for Clinial Laboratory Standards recommendation that the commercially available hemagglutination inhibition assays for erythropoietin not be used for clinical purposes.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with erythropoietin assays.

5. Risk to health: (a) Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the differential diagnosis between secondary polycythemia, and polycythemia vera. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. A misdiagnosis of polycythemia vera could unecessarily subject the patient to potentially harmful chemotherapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that erythropoietin assays be classified into class III (premarket approval). An FDA review of medical literature concerning erythropoietin assays has found evidence that a sufficiently sensitive and specific in vitro erythropoietin assay has yet to be developed (Refs. *1* and *2*). The difficulty with immunological assays lies in obtaining an antigen of the required concentration and purity (Refs. *2, 3,* and *4*). Unless the erythropoietin is very pure, the immunological reactions observed are likely to be due to contamination (Ref. *2*). Available in vivo animal assays are not suitable for measuring very low levels of erythropoietin (Refs. *2* and *5*).

The effectiveness of erythropoietin assay methods is limited by the lack of an acceptable erythropoietin reference. Although erythropoietin Standard B is the International Reference Preparation for Erythropoietin (Ref. *2*), a study conducted by Dukes, Hammond and Shore (Ref. *6*) shows that this reference preparation is not sufficiently pure or sufficiently concentrated. These devices are purported or represented for use in the diagnosis of polycythemia vera, a potentially fatal disease. The FDA believes that the use of the assay for this purpose presents a potential unreasonable risk of illness or injury to the patient if inaccurate diagnostic information results in a failure to diagnose polycythemia vera. The agency believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Wintrobe, M. M., G. R. Lee, D. R. Boggs, T. C. Bithell, J. W. Athens, and J. Foerster, "Clinical Hematology," 7th Ed., Lea and Febiger, Philadelphia, p. 975, 1974.

2. Miale, J. B., "Laboratory Medicine Hematology," C. V. Moseby Co., St. Louis, pp. 20–25, 1977.

3. Krugers Dagneaux, P. G. L. C., R. Goudsmit, and H. W. Krijnen, "Investigations on an Immunoassay of Erythropoietin," *Annals of the New York Academy of Science.* 149:294–297, 1968.

4. Lange, R. D., T. P. McDonald, and T. Jordan, "Antisera to Erythropoietin: Partial Characterization of Two Different Antibodies," *Journal of Laboratory and Clinical Medicine,* 73:79–90, 1969.

5. Erslev, A. J., "Erythropoietin Assay," *in* "Hematology," 2d Ed., Edited by W. J. Williams, McGraw-Hill Book Co., New York, pp. 1616–1618. 1977.

6. Dukes, P. P., D. Hammond, and N. A. Shore, "Comparison of Erythropoietin Preparations Yielding Different Dose-Response Slopes in the Exhypoxic Polycythemic Mouse Assay," *Journal of Laboratory and Clinical Medicine,* 74:250–256, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21

U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed to amend Part 864 in Subpart H by adding new § 864.7250 as follows:

§ 864.7250 Erythropoietin assay.

(a) *Identification.* An erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27661 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1882]

Medical Devices; Classification of Euglobulin Lysis Time Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying euglobulin lysis time tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of euglobulin lysis time Tests:

1. Identification: A euglobulin lysis time test is a device that measures the length ot time required for the lysis (dissolution) of a clot formed from fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysing enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that euglobulin lysis time tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience and familarity with this test and upon an article by Chakrabarti et al. (Ref. *1*) stating that this test is widely used, but that its reproducibility is dependent upon the pH and temperature of the euglobulin fraction and suspending buffer and the anticoagulant used to collect the blood.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a disease process such as disseminated intravascular coagulation (a potentially life-threatening condition which may be characterized by shock, bleeding, and vessel blockage) or primary fibrinolysis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The patient may be subjected unnecessarily to potentially hazardous therapy.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that euglobulin lysis time tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A standard addressing the pH, temperature, and anticoagulant used in the assay will provide reasonable assurance of the safety and effectiveness of the assay. The agency also believes that there is sufficient information to establish a standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Chakrabarti, R. et al., "Methodological Study and a Recommended Technology for Determining Euglobulin Lysis Time," *Journal of Clinical Pathology*, 21:698–701, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Foods and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7275 as follows:

§ 864.7275 Euglobulin lysis time test.

(a) *Identification.* A euglobulin lysis time test is a device that measures the length of time required for the lysis (dissolution) of a clot formed from

fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysing enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27662 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1883]

Medical Devices; Classification of Factor Deficiency Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying factor deficiency tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of factor deficiency tests:

1. Identification: A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor deficiency such as hemophilia and the corresponding normal gene).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel Recommends that factor deficiency tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. Because the plasmas used as substrates are obtained from multitransfused patients, there is a very high hepatitis B risk. The Panel recommends that the device be required to bear labeling which indicates the level of factor substrate that is present and to warn the user of the high risk of hepatitis B infection from contact with the substrate.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with factor deficiency tests.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a bleeding disorder or in the failure to detect coagulation inhibitors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. In addition, there is a risk of postoperative hemorrhage from an undetected bleeding disorder. (b) Hepatitis infection: Exposure of the user to the substrate presents a risk of hepatitis B infection.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that the factor deficiency tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7290 as follows:

§ 864.7290 Factor deficiency test.

(a) *Identification.* A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor deficiency such as hemophilia and the corresponding normal gene).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this

document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27663 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1884]

Medical Devices; Classification of Fibrin Monomer Paracoagulation Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fibrin monomer paracoagulation tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fibrin monomer paracoagulation tests:

1. Identification: A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that fibrin monomer paracoagulation tests be classified into Class II to assure control over the purity of the protamine sulfate used in the test. Impure protamine sulfate causes the user to detect varying concentrations of fibrin monomer. This variability affects the test's accuracy and sensitivity and the interpretation of the test results. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that the device be required to bear labeling which indicates the lowest level of fibrin monomer that the device can detect.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with this test and upon an article by Kidder et al. (Ref. *1*) which evaluated the sensitivity of the test and the effects of fibrinogen concentration, fibrin degradation products, anticoagulants, temperature, and plasma storage conditions. Kidder and his coworkers concluded that this test should be included in any screening procedures in cases of suspected intravascular coagulation.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disseminated intravascular coagulation, a potentially life-threatening condition which may be characterized by shock, bleeding, and vessel blockage. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that fibrin monomer paracoagulation tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kidder, W. R. et al., "The Plasma Protamine Paracoagulation Test: Clinical and Laboratory Evaluation," *American Journal of Clinical Pathology*, 58:675-686, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7300 as follows:

§ 864.7300 Fibrin monomer paracoagulation test.

(a) *Identification.* A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27664 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1885]

Medical Devices; Classification of Fibrin Split Products Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fibrin split products assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that this device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with regard to the classification of fibrin split products assays:

1. Identification: A fibrin split products assay is a device used to detect and quantitate fibrin split products (protein fragments produced by the enzymatic action of plasmin on fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that fibrin split products assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that the labeling for those kits employing the staphylococcal clumping methodology be required to include precautions regarding the potential for staphylococcal infection from the use of this device.

4. Summary of data on which the recommendations are based: The Panel based its recommendations upon the Panel members' clinical experience and upon medical literature concerning fibrin split products (Refs. *1* and *2*). The literature shows that current methods are usually too complex and time consuming for clinical use and that they lack the required sensitivity. Recent improvements in the fibrin plate and latex agglutination methods have overcome some of these limitations (Refs. *1* and *2*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disseminated intravascular coagulation, a potentially life-threatening condition which may be characterized by shock bleeding, and vessel blockage. Inappropriate therapy, e.g., unnecessary administration of heparin in the treatment of venous thrombosis, based on inaccurate diagnostic data may place the patient at risk. (b) Staphylococcal infection: The user faces a risk of staphylococcal infection from the kit materials.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that fibrin split product assays be classified into Class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 5 p.m., Monday through Friday.

1. Ellman, L., A. Carvalho, and R. W. Colman, "The Thrombo-Wellcotest as a Screening Test for Disseminated Intravascular Coagulation," *New England Journal of Medicine,* 288:633-634, 1973.

2. Bishop, R., et al., "The Preparation and Evaluation of a Standardized Fibrin Plate for the Assessment of Fibrinolytic Activity," *Thrombosis et Diathesis Haemorrhagica* (Stuttgart), 23(2):201-210, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7320 as follows:

§ 864.7320 Fibrin split products assay.

(a) *Identification.* A fibrin split products assay is a device used to detect and quantitate fibrin split products (protein fragments produced by the enzymatic action of plasmin on fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600

Fishers Lane, Rockville, MD 20857. written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27665 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1886]

Medical Devices; Classification of Fibrinogen Determination Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fibrinogen determination systems into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel and the Immunology Device Classification Panel that this device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Immunology Device Classification Panel, two FDA advisory committees, made the following recommendations with respect to the classification of fibrinogen determination systems:

1. Identification: A fibrinogen determination system is a device that consists of the instruments, reagents, standards, and controls used to determine the fibrinogen levels in disseminated intravascular coagulation (nonlocalized clotting within the blood vessels) and primary fibrinolysis (the dissolution of fibrin in a blood clot). The Panels identified this generic device under the names "fibrinogen test," "fibrinogen determination standards and controls," "fibrinogen and split products, antigen, antiserum, control," "fibrinogen and fibrin split products, antigen, antiserum, control," "fibrinogen and split products, FITC, antigen, antiserum, control," "fibrinogen and split products, peroxidase, antigen, antiserum, control," and "fibrinogen and split products, rhodamine, antigen, antiserum, control."

2. Recommended classification: The Hematology Device Classification Panel recommends that the "fibrinogen test" and "fibrinogen determination standards and controls" be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Immunology Device Classification Panel recommends that "fibrinogen and split products antigen, antiserum, control," "fibrinogen and fibrin split products, antigen, antiserum, control," "fibrinogen and split products, FITC, antigen, antiserum, control," "fibrinogen and split products, peroxidase, antigen, antiserum, control," and "fibrinogen and split products, rhodamine, antigen, antiserum, control" be classified into class II and that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that fibrinogen determination systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Immunology Device Classification Panel recommends that fibrinogen determination systems be classified into class II because their reliability will be better assured by controls over the sensitivity, specificity, and stability of the reagents used in them. Lack of adequate sensitivity, specificity, or stability may cause a malfunction that results in an erroneous diagnosis and patient mismanagement. Both Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations upon the Panel members' clinical experience with this product and the medical literature concerning fibrinogen determination (Refs. *1* through *5*). Fibrinogen is essential for blood clot formation because it is the protein that is converted to fibrin, the basic substance from which the clot is formed. Fibrinogen disorders include: afibrinogenemia (an absence of fibrinogen), hypofibrinogenemia (low levels of fibrinogen), and dysfibrinogenemia (normal levels of fibrinogen but with defective fibrinogen). An acquired deficiency is associated with some liver disorders. The Panels considered evaluations of various methods for determining plasma fibrinogen (Refs. *1* through *5*). Evaluations of nonimmunologic methods showed that the clottable protein methodology is superior in terms of accuracy, reproducibility, specificity, and preventing effects from interfering substances. This method does, however, have limitations. It is complex, presents a potential for error if not performed carefully, and is too time consuming for use in emergency situations. The precipitable protein method is considered unreliable, nonquantitative, nonspecific, and subject to large errors. Antigen-antibody systems for estimating plasma fibrinogen are specific, offer the advantage of requiring only small amounts of plasma, and provide good recovery for fibrinogen values in the low range. Immunologic methods allow the user to distinguish dysfibrinogenemia from hypofibrinogenemia. In general, fibrinogen tests are not standardized because of the lack of a quick, simple

reference method. The Hematology Device Classification Panel indicated that the Center for Disease Control is working in conjunction with the International Committee for Standardization in Hematology (ICSH) and the International Committee on Thrombosis and Hemostasis to standardize fibrinogen determination on an international basis.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a bleeding disorder or disseminated intravascular coagulation (nonlocalized clotting within the blood vessels), a potentially life-threatening condition which may be characterized by shock, bleeding, and vessel blockage. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The risks include bleeding, kidney failure, and unnecessary therapy. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that fibrinogen determination systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Filip, D. J., J. D. Eckstein, and C. A. Sibley, "Observations and Diagnostic Kits for the Determination of Plasma Fibrinogen," *American Journal of Clinical Pathology*, 62:32–39, 1974.

2. Stevens, D. J. and M. J. Sanfelippo, "Evaluation of Three Methods for Plasma Fibrinogen Determination," *American Journal of Clinical Pathology*, 60:182–187, 1973.

3. Grannis, G. F., "Plasma Fibrinogen: Determination, Normal Values, Physiologic Shifts, and Fluctuations," *Clinical Chemistry*, 16(6):486, 1970.

4. Chen, T. and C. H. Lai, "Fibrinogen Assay by an Immunodiffusion Plate," *American Journal of Clinical Pathology*, 52(5):629–630, 1969.

5. Alkjaersig, N., A. Fletcher, and R. Burstein, "Association Between Oral Contraceptive Use and Thromboembolism: A New Approach to Its Investigation Based on Plasma Fibrinogen Chromatography," *American Journal of Obstetrics and Gynecology*, 122(2):199–211, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7340 as follows:

§ 864.7340 Fibrinogen determination system.

(a) *Identification.* A febrinogen determination system is a device that consists of the instruments, reagents, standards, and controls used to determine the fibrinogen levels in disseminated intravascular coagulation (nonlocalized clotting within the blood vessels) and primary fibrinolysis (the dissolution of fibrin in a blood clot).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27666 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1887]

Medical Devices; Classification of Erythrocytic Glucose-6-Phosphate Dehydrogenase Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying erythrocytic glucose-6-phosphate dehydrogenase assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel and the Clinical Chemistry Device Classification Panel that this device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Clinical Chemistry Device Classification Panel, two FDA advisory committees, made the following recommendation with respect to the classification of erythrocytic glucose-6-phosphate dehydrogenase assays:

1. Identification: An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultraviolet kinetics. The Hematology Device Classification Panel identified this generic device under the names "glucose-6-phosphate dehydrogenase (erythrocytic), catalase inhibition," "glucose-6-phosphate dehydrogenase (erythrocytic), methemoglobin reduction," and

"glucose-6-phosphate dehydrogenase (erythrocytic), quantitative." The Clinical Chemistry Device Classification Panel identified this generic type device under the names "NADP reduction (ultraviolet) glucose-6-phosphate dehydrogenase," visual semi-quantitative (colorimetric) glucose-6-phosphate dehydrogenase," and "electrophoretic, glucose-6-phosphate dehydrogenase isoenzymes."

2. Recommended classification: The Hematology Device Classification Panel recommends that "glucose-6-phosphate dehydrogenase (erythrocytic), catalase inhibition," "glucose-6-phosphate dehydrogenase (erythrocytic), methemoglobin reduction," and "glucose-6-phosphate dehydrogenase (erythrocytic), quantitative," be classified into class II and that establishing a performance standard for these devices be a medium priority. The Clinical Chemistry Device Classification Panel recommends that "NADP reduction (ultraviolet) glucose-6-phosphate dehydrogenase" and "visual semi-quantitative (colorimetric) glucose-6-phosphate dehydrogenase" be classified into class II and that establishing a performance standard for these devices be a low priority. The Clinical Chemistry Device Classification Panel recommends that "electrophoretic, glucose-6-phosphate dehydrogenase isoenzymes" be classified into class II and that establishing a performance standard be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that erythrocytic glucose-6-phosphate dehydrogenase assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The diagnostic information derived from the use of these devices is the basis for diagnosis and treatment of hemolytic anemias and of hemolytic disease of the newborn, which are potentially life-threatening conditions. The Hematology Device Classification Panel recommends that the product's labeling be required to state that this test is not specific for glucose-6-phosphate dehydrogenase deficiency, and that it may not be reliable in the diagnosis of a heterozygous glucose-6-phosphate dehydrogenase deficiency state.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' clinical experience with this assay, which indicates that it is most useful in the evaluation of certain genetic hemolytic anemias. The Panels noted that standardized procedures for the study of glucose-6-phosphate dehydrogenase have been developed by the World Health Organization (Ref. *1*) and the International Committee for Standardization in Hematology (Ref. *2*).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hemolytic anemia caused by drugs or by a genetic defect. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The risks include inappropriate drug therapy, contraindicated splenectomy, and unnecessary transfusions.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that erythrocytic glucose-6-phosphate dehydrogenase assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Betke, K. et al., "Standardization of Procedures for the Study of Glucose-6-Phosphate Dehydrogenase. Report of a WHO Scientific Group," WHO Technical Report Series, 366, 1967.

2. Beutler, E. et al., "International Committee for Standardization in Haematology: Recommended Methods for Red-Cell Enzyme Analysis," *British Journal Haematology*, 35:331–340, 1977.

3. Beutler, E., "Glucose-6-Phosphate Dehydrogenase Deficiency, Diagnosis, Clinical and Genetic Implications, *"American Journal of Clinical Pathology*, 47(3): 303–311, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7360 as follows:

§ 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.

(a) *Identification.* An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of non-spherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultravioloet kinetics.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27667 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1888]

Medical Devices; Classification of Glutathione Reductase Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying glutathion reductase assays

into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel and the Clinical Chemistry Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Clinical Chemistry Device Classification Panel, two FDA Advisory committees, made the following recommendations with respect to the classification of glutathione reductase assays:

1. Identification: A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this test are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency. The Hematology Device Classification Panel identified that device as the "glutathione, red cell." The Clinical Chemistry Device Classificiation Panel identified this device as "fluorescence, visual observation (qualitative ultraviolet) glutathione reductase."

2. Recommended classification: The Hematology Device Classification Panel recommends that "glutathione, red cell," be classified into Class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Clinical Chemistry Device Classification Panel recommends that "fluorescence visual observation (qualitative ultraviolet) glutathione reductase" be classified into Class II and that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that glutathione reductase assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panels believe that general controls would not provide sufficient control over this characteristic. The Panels believe that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' clinical experience, which indicates that this assay is most useful in a differential diagnosis between riboflavin deficiency and congenital glutathione reductase deficiency. The Panel noted that a standard for red cell glutathione has been developed by the International Committee for Standardization in Hematology (Ref. *1*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of liver disease, congenital glutathione reductase deficiency, or riboflavin deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that glutathione reductase assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Beutler, E., et al., "International Committee for Standardization in Haematology: Recommended Methods for Red-Cell Enzyme Analysis," *British Journal of Haematology*, 35:331–340, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7375 as follows:

§ 864.7375 Glutathione reductase assay.

(a) *Identification.* A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27668 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N-1889]

Medical Devices; Classification of Hemoglobin A_2 Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the hemoglobin A_2 assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hemoglobin A_2 assays:

1. Identification: A hemoglobin A_2 assay is a device used to determine the hemoglobin A_2 content of human blood. The measurement of hemoglobin A_2 is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chain). Electrophoresis or column chromatography is used to make this measurement.

2. Recommended Classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hemoglobin A_2 assays be classified into class II because there is a need for a performance standards that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unncessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with this assay and the medical literature. The Panel stated that the International Committee for Standardization in Haematology (ICSH) has recommended methods for hemoglobin A_2 quantitation and a hemoglobin A_2 reference preparation (Ref. *1*). The ICSH recommendation concerns the pH and type of buffer, support media, electrical voltage applied, and duration of electrophoresis. The Panel also cited a 1973 study which showed excessive interlaboratory variability in the quantitation of hemoglobin A_2 (Ref. *2*). To solve this problem, the study recommended the adoption of a standard method for hemoglobin A_2 quantitation. The Panel also considered evaluations of the available methodology for the estimation of hemoglobin A_2 and (Ref. *3*) for large scale screening for hemoglobin A_2 (Ref. *4*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin abnormality. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk (b) Electrical shock: The user faces the risk of electrical shock from the electrophoretic chamber and power supply of the device.

Proposed Classification

FDA agress with the Panel's recommendation and is proposing that hemoglobin A_2 assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Haematology, "Recommendations for Selected Methods for Quantitative Estimation of Hb A_2 and for Hb A_2 Reference Preparation," *British Journal of Haematology*, 38:573, 1978.

2. White, J. M., "Haemoglobin A_2 Estimation," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 19-24, 1975.

3. Shibata, S., T. Miyaji and Y. Ohba, "Evaluation of Precision of Procedures for Estimation of Hb A_2 and Hb F in Hemolysates," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 25-32, 1975.

4. Huntsman, R. G., and D. McLellan, "The Estimation of Foetal Hemoglobin and Hemoglobin A_2: An Evaluation of Available Technology Suitable for Large Scale Screening," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 247-265, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7400 as follows:

§ 864.7400 Hemoglobin A_2 assay.

(a) *Identification:* A hemoglobin A_2 assay is a device used to determine the hemoglobin A_2 content of human blood. The measurement of hemoglobin A_2 is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypetide chain).

Electrophoresis or column chromatography is used to make this measurement.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27669 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1890]

Medical Devices; Classification of Abnormal Hemoglobin Assays

AGENCY: Food and Drug Adminstration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying abnormal hemoglobin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Adminstration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of abnormal hemoglobin assays:

1. Identification: An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types. The Panel identified this generic type of device as "hemoglobin, abnormal, quantitation" and "abnormal hemoglobin control."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that abnormal hemoglobin assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel noted that a quality control material is one of the most critical products in the hematology laboratory. The laboratory relies upon this material to determine whether its instrumentation is functioning properly. The development of a performance standard for the abnormal hemoglobin control is essential to the improvement of quality control in hemoglobinometry (the measurement of the hemoglobin in the blood). The allowed variation in the control's stated value must not be so wide as to make that value meaningless. The control's labeling should be required to list those instruments for which the product will give valid results. The abnormal hemoglobin control should never be used for calibration purposes. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with this device and upon evaluations of current screening methods, including electrophoresis, heat stability, isopropanol, and staining (Refs. *1* and *2*). The Panel stated that recommended methods for the identification of abnormal hemoglobins and an abnormal hemoglobin reference preparation have been developed by the International Committee for Standardization in Haematology (ICSH) (Refs. *3* and *4*). The ICSH recommendation addresses pH, electrolyte, support media, electrical voltage applied, and duration of electrophoresis.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin abnormality. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Electrical shock: The user faces the risk of electrical shock from the elctrophoretic chamber and power supply of the device.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that abnormal hemoglobin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performnce standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Schneider, R. G. and R. M. Schmidt, "Electrophoretic Screening for Abnormal Hemoglobins," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 33–63, 1975.

2. Kleihauer, E. and E. Kohne, "Application of the Acid Elution Technique for the Detection of Inclusion Bodies," *in* "Abnormal

Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 149–159, 1975.

3. International Committee for Standardization in Haematology, Recommendations of a System for Identifying Abnormal Hemoglobins," *Blood*, 52(5): 1065–1067, 1978.

4. International Committee for Standardization in Haematology, "Recommendations for Abnormal Haemoglobin Standard," *British Journal of Haematology*, 35:161, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7415 as follows:

§ 864.7415 Abnormal hemoglobin assay.

(a) *Identification.* An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27670 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1891]

Medical Devices; Classification of Carboxyhemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carboxyhemoglobin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of carboxyhemoglobin assays:

1. Identification: A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that Carboxyhemoglobin assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with carboxyhemoglobin and the medical literature. Van Assendelft discusses the absorption spectrum of carboxyhemoglobin and spectrophotometric methods for the determination of carbon monoxide saturation in suspected carbon monoxide poisoning (Ref. *1*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of carbon monoxide poisoning. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Electrical shock: If the spectrophotometer malfunctions, the user faces the risk of electrical shock.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that carboxyhemoglobin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Van Assendelft, O. W., "Spectrophotometry of Hemoglobin Derivatives," Charles C. Thomas Co., Springfield, Ill., pp. 59–61, 125–128, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority

delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7425 as follows:

§ 864.7425 Carboxyhemoglobin assay.

(a) *Identification:* A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27671 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1892]

Medical Devices; Classification of Electrophoretic Hemoglobin Analysis Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrophoretic hemoglobin analysis systems into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel and the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrophoretic hemoglobin analysis systems:

1. Identification: An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies normal and abormal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for th's device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electrophoretic hemoglobin analysis systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes that possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with electrophoretic methods for hemoglobin analysis and the medical literature. The Panel stated that voluntary standards currently exist. The International Committee for Standardization in Hematology (ICSH) has recommended a system for the identification of abnormal hemoglobins by electrophoretic procedures (Ref. *1*). The ICSH system specifies pH, electrolyte, support media, voltage applied, and the duration of electrophoresis. The ICSH has also developed a reference preparation of abnormal hemoglobins suitable for the standardization of electrophoresis (Ref. *2*). The Center for Disease Control (CDC) has published methods for hemoglobin electrophoresis (Ref. *3*). The National Committee for Clinical Laboratory Standards (NCCLS) has drafted a proposed standard for hemoglobin electrophoresis (Ref. *4*). The Panel also relied upon evaluations of electrophoretic methods for abnormal hemoglobin screening (Refs. *5* and *6*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin abnormality. Inappropriate therapy based on inaccurate diagnositc data may place the patient at risk. (b) Electrical shock: The user faces the risk of electrical shock from the electrophoretic chamber and power supply of the device.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that electrophoretic hemoglobin analysis systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Hematology,

"Recommendations of a System for Identifying Abnormal Hemoglobins," *Blood*, 52(5): 1065–1067, 1978.

2. International Committee for Standardization in Hematology, "Recommendations for Abnormal Hemoglobin Standard," *British Journal of Haematology*, 37:161, 1977.

3. Schmidt, R. M. and E. M. Brosious, "Basic Laboratory Methods of Hemoglobinopathy Detection," DHEW Publication No. (CDC) 76–8266, pp. 32–37, 1976.

4. Schmidt, R. M. Report to the Board of Directors of the NCCLS, June 1978.

5. Schneider, R. G. and R. M. Schmidt, "Electrophoretic Screening for Abnormal Hemoglobins," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 33–63, 1975.

6. Huntsman, R. G. and D. McLellan, "The Estimation of Foetal Haemoglobin and Haemoglobin A_2: An Evaluation of Available Technology Suitable for Large Scale Screening," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 247–265, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 864 in Subpart H by adding new § 864.7440 as follows:

§ 864.7440 Electrophoretic hemoglobin analysis system.

(a) *Identification:* An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies abnormal and normal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.

(b) *Classification:* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27672 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N–1893]

Medical Devices; Classification of Fetal Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fetal hemoglobin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fetal hemoglobin assays:

1. Identification: A fetal hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells in the maternal circulation or to detect elevated levels of fetal hemoglobin in hemoglobin abnormalities such as thalassemia (a hereditary hemolytic anemia characterized by decreased synthesis of one or more types of hemoglobin polypeptide chain). The hemoglobin determination may be made by means of such methodologies as electrophoresis, alkali denaturation, column chromatography, and radial immunodiffusion. The Panel identified this generic device as "fetal hemoglobin stains" and "hemoglobin F quantitation."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that fetal hemoglobin assays be classified into class II because there is a need for a performance standard that prescribed for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places that patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that the labeling include specific directions for the use of positive and negative controls and for the calculation of the percent of the fetal cells in the mother's blood.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with fetal hemoglobin determinations and on the medical literature. The Panel stated that voluntary standards for fetal hemoglobin currently exist. The International Committee for Standardization in Hematology (ICSH) has recommended a system for the identification of abnormal hemoglobins, including fetal hemoglobin (Ref. *1*). A reference preparation of abnormal hemoglobins prepared by the ICSH includes fetal hemoglobin (Ref. *2*). The Center for Disease Control (CDC) has

published methods for the detection of fetal hemoglobin (Ref. *3*). The National Committee for Clinical Laboratory Standards (NCCLS) has drafted a proposed standard for fetal hemoglobin (Ref. *4*). In making its recommendation the Panel considered evaluations of the present technology for large scale screening for hemoglobin (Refs. *5* and *6*). These evaluations concerned both manual and automated techniques, including those of Betke, (Ref. *7*), the alkali denaturation test, and column chromatography.

5. Risks to health: (a) Failure to detect fetal Rh prositive cells in the mother's blood: An erroneous result may cause the failure to detect fetomaternal transfusions of Rh positive cells that have have sensitized or that will sensitize the mother. This could result in failure to protect an unborn fetus. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin abnormality such as thalassemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (c) Electrical shock: The user faces the risk of electrical shock from the electrophoretic chamber and power supply of the electrophoresis device.

Proposed Classification

FDA agrees wtih the Panel's recommendation and is proposing that fetal hemoglobin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Hematology, "Recommendations of a System for Identifying Abnormal Hemoglobins," *Blood*, 52(5):1065–1067, 1978.

2. International Committee for Standardization in Haematology,"ICSH Recommendations for Abnormal Haemoglobin Standard," *British Journal of Haematology, 35.161, 1977.*

3. Schmidt, R. M. and E. M. Brosious, "Basic Laboratory Methods of Hemoglobinopathy Detection," DHEW Publication No. (CDC) 76–8266, pp. 46–51, 1976.

4. Schmidt, R. M., Report to the Board of Directors of the NCCLS, June 1978.

5. Shibata, S., T. Miyaji, and Y. Ohba, "Evaluation of Precision of Procedures for Estimation of HbA_2 and HbF in Hemolysates," in "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 25–32, 1975.

6. Huntsman, R. G. and D. McLellan, "The Estimation of Foetal Haemoglobin and Haemoglobin A_2: An Evaluation of Available Technology Suitable for Large Scale Screening," in "Abornmal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press, Inc., New York, pp. 247–265, 1975.

7. Kleihauer, E., H. Braun, and K. Betke, "Demonstration von Fetalem Haemoglobin in Den Erythrocyten Eines Blutausstrichs," *Klinische Wochenschrift*, 35(12):637, 1957.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7455 as follows:

§ 864.7455 Fetal hemoglobin assay.

(a) *Identification:* A hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells on the maternal circulation or to detect elevated levels or fetal hemoglobin in hemoglobin abnormalities such as thalassemia (a hereditary hemolytic anemia characterized by a decreased synthesis of one of more types of hemoglobin polypeptide chain). The hemoglobin determination may be made by means of methodologies such as electrophoresis, alkali denaturation, column chromatography, and radial immunodiffusion.

(b) *Classification.* Class II (performan e standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27673 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1895]

Medical Devices; Classification of Sulfhemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying sulfhemoglobin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of sulfhemoglobin assays:

1. Identification: A sulfhemoglobin assay is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the sulfhemoglobin (a compound of sulfur

and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that sulfhemoglobin assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with sulfhemoglobin and the medical literature. Van Assendelft discussed the spectral properties of sulfhemoglobin and methods for the determination and estimation of sulfhemoglobin saturation in detecting sulfhemoglobinemia (Ref. 1).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of sulfhemoglobinemia. Inappropriate therepy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that sulfhemoglobin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Van Assendelft, O. W., "Spectrophotometry of Haemoglobin Derivatives," Charles C. Thomas Co., Springfield, Ill., pp. 74–85, 129–130, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7490 as follows:

864.7490 Sulfhemoglobin assay.

(a) *Identification.* A sulfhemoglobin assay is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305). Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27674 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1896]

Medical Devices; Classification of Whole Blood Hemoglobin Assays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying whole blood hemoglobin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. The actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of whole blood hemoglobin assays:

1. Identification: A whole blood hemoglobin assay is a device consisting of reagents, calibrators, controls, and photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that whole blood hemoglobin assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with hemoglobin assays. The Panel stated that the International Committee for Standardization in Hemotology (ICSH) has recommended a cyanmethemoglobin method and a cyanmethemoglobin reference standard (Ref. *1*). The method and reference standard have been accepted by the College of American Pathologists, the American Society of Hematology, and the National Committee for Clinical Laboratory Standards. In making its recommendation, the Panel also relied upon the medical literature concerning hemoglobinometry. Van Assendelft discusses the standardization of hemoglobinometry and photometric errors (Ref. *2*). Van Assendelft, Zijlstra, and van Kampen discuss the sources of error in the cyanmethemoglobin method, including improper technique in obtaining and diluting the blood sample, storage of reagents in improper containers, accidental freezing of reagents and improper preparation of reagents (Ref. *3*). In addition, the hemoglobin determination may be in error if the measuring instrument is not calibrated and checked with a cyanmethemoglobin reference solution (Ref. *3*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a hemoglobin disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. These data may be the basis for a decision to initiate or stop treatment, including blood transfusion. (b) Potassium cyanide hazard: The potassium cyanide present in some hemoglobin reagents constitutes a hazard to the user. (c) Electrical shock: The user faces the risk of electrical shock from a malfunction of the photometer or spectrophotometer employed to measure the hemoglobin content of the blood.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that whole blood hemoglobin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "International Committee for Standardization in Haematology, Recommendations for Haemoglobinometry in Human Blood," *British Journal of Haematology*, 13 (Supplement): 71, 1967.

2. Van Assendelft, O. W. "Spectrophotometry of Haemoglobin Derivatives," Charles C. Thomas Co., Springfield, IL, pp. 35–38, 86–118, 1970.

3. Van Assendelft, O. W., W. G. Zijlstra, and E. J. van Kampen, "Haemoglobinometry: Challenges and Pitfalls," *Proceedings Koninklijke, Nederlandse Akademia van Wetenschappen*, 73:104–112, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7500 as follows:

§ 864.7500 Whole blood hemoglobin assay.

(a) *Identification:* A whole blood hemoglobin assay is a device consisting of reagents, calibrators, controls, and photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27875 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1897]

Medical Devices; Classification of Heparin Assays

AGENCY: Food and Drug Administration.

ACTION: Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heparin assays into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of heparin assays:

1. Identification: A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures utilizing the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin). The Panel identified this generic type of device as "heparin assays, clotting time," "the heparin neutralization test," and "protamine sulfate."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that heparin assays be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with heparin assays and upon a description of the use of a heparin assay to determine the dosage of protamine sulfate required to neutralize the heparin in the patient's circulation (Ref. *1*).

5. Risks to health: Hemorrhage or thromboembolism: If this device incorrectly reports the level of heparin in the patient's blood, hemorrhage or thrombosis may result because of administration of an inappropriate amount of protamine.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that heparin assays be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hardisty, R. M., and G. I. C. Ingram, "Bleeding Disorders," R. A. Davis Co., Philadelphia, PA, pp. 152–158, 320–322, 1965.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7525 as follows:

§ 864.7525 Heparin assay.

(a) *Identification.* A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures utilizing the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

(b) *Classification.* Class II (performance standards). Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27676 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1898]

Medical Devices; Classification of Leukocyte Alkaline Phosphatase Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying leukocyte alkaline phosphatase tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of leukocyte alkaline phosphatase tests:

1. Identification: A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic

granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occurring in severe infections and polycythemia (increased total red cell mass).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that leukocyte alkaline phosphatase tests be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with these tests. The Panel believes that is is an accepted fact that stains are mixtures of compounds which are hard to standardize and often vary greatly from one lot to the next. It has been the Panel members' experience that 10 to 25 percent of stain lots are unusable.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in diagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk unnecessarily. Poor staining characteristics may lead to any of the following: (a) Failure to detect leukocyte alkaline phosphatase in various leukemoid states (conditions resembling true leukemia); (b) Inability to differentiate leukemoid-reactive cells; (c) Improper classification of a leukemia process; and (d) Inability to classify an anemia, polycythemia, or infection.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that leukocyte alkaline phosphatase tests be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that users can avoid poor staining characteristics by paying close attention to fixing, staining, rinsing, and drying the slides, and by staining control slides to assure that the stain is working properly.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7660 as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

(a) *Identification:* A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granuloctyes in the bone marrow) and reactions that resemble true leukemia, such as those occurring in severe infections and polycythemia (increased total red cell mass).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27677 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1899]

Medical Devices; Classification of Leukocyte Peroxidase Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying leukocyte peroxidase tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of leukocyte peroxidase tests:

1. Identification: A leukocyte peroxidase test is a device used to distinguish certain myeloid cells (cells derived from the bone marrow i.e., neutrophils, eosinophils, and monocytes) from lymphoid cells (cells of the lymphatic system) and erythroid cells (cells in the red blood cell series) on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that leukocyte peroxidase tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' clinical experience with this test. The Panel believes that it is an accepted fact that stains are mixtures of compounds which are hard to standardize and often vary greatly from one lot to the next. It has been the Panel members' experience that 10 to 25 percent of stain lots are unusable.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily may lead to an error in diagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Poor staining characteristics may lead to any of the following: (a) Failure to detect peroxidase-positive cells of the granulocytic series; (b) Failure to detect peroxidase-negative cell types; and (c) Improper classification of a leukemic process.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that leukocyte peroxidase tests be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that users can avoid poor staining characteristics by paying close attention to staining, rinsing, and drying the slides and by staining control slides to assure that the stain is working properly.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7675 as follows:

§ 864.7675 Leukocyte peroxidase test.

(a) *Identification.* A leukocyte peroxidase test is a device used to distinguish certain myeloid cells (cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes) from lymphoid cells (cells of the lymphatic system) and erythroid cells (cells in the red blood cell series) on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27678 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1900]

Medical Devices; Classification of Prothrombin Consumption Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prothrombin consumption tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prothrombin consumption tests:

1. Identification: A prothrombin consumption test is a device that measures the patient's capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that prothrombin consumption tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. An abnormal result for the prothrombin consumption test indicates a platelet dysfunction, a lack of plasma thromboplastin precursor activity, which causes reduced plasma thromboplastin activity, or both. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a coagulation defect or platelet abnormality. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that prothrombin consumption tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide

reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7720 as follows:

§ 864.7720 Prothrombin consumption test.

(a) *Identification.* A prothrombin consumption test is a device that measures the patient's capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27679 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1901]

Medical Devices; Classification of Prothrombin-Proconvertin Tests and the Thrombotests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prothrombin-proconvertin tests and the thrombotests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prothrombin-proconvertin tests and thrombotests:

1. Identification: The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anti-coagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that prothrombin-proconvertin tests and the thrombotests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unncessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with these tests and the medical literature. An evaluation of the thrombotest indicates that it was developed to be sensitive to a deficiency in a patient's blood of the coagulation factor X (Stuart factor) and that, in this respect, the thrombotest is superior to the prothrombin-proconvertin test (Ref. *1*). Although the thrombotest is not intended to diagnose hemophilia, it can indicate depressed levels of the coagulation factor IX (plasma thromboplastin component). A study by Rapaport and Ames (Ref. *2*) revealed significant differences in the prothrombin time as measured by the prothrombin-proconvertin method and a modified Quick prothrombin method.

5. Risks to health: (a) Hemorrhage or thrombosis in patients undergoing sodium warfarin therapy: If this device fails to perform satisfactorily, hemorrhage or thrombosis could result due to the administration of an inappropriate amount of the anticoagulant sodium warfarin. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of deficiencies of coagulation factors II (prothrombin), VII (proconvertin), or IX (plasma thromboplastin compenent). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. An undiagnosed coagulation factor deficiency may cause bleeding during surgery.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that prothrombin-proconvertin tests and thrombotests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that

there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Owren, P. A., "Control of Anticoagulant Therapy, the Use of New Tests," *Archives of Internal Medicine*, 111:248–258, 1963.

2. Rapaport, S. I., and S. B. Ames, "Relation Between Levels of Plasma Thromboplastin Component (PTC) and Prothrombin Times by the P and P and Quick Methods in Patients Receiving Warfarin, "*New England Journal of Medicine*, 267:125–130, 1962.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7735 as follows:

§ 864.7735 Prothrombin-proconvertin test and thrombotest.

(a) *Identification.* The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place, of the Quick prothrombin time test to detect coagulation disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Recieved comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27680 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1902]

Medical Devices; Classification of Prothrombin Time Tests

AGENCY: Food and Drug Administration.

ACTION: Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prothrombin time tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prothrombin time tests:

1. Identification: A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that prothrombin time tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information: Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The prothrombin time test is often used for the presurgical screening of patients for potential bleeding problems. The panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with the prothrombin time test and the medical literature. The Center for Disease Control is working with the International Committee for Standardization in Hematology and the International Committee on Thrombosis and Haemostasis (ICTH) to standardize this test (Ref. *1*). The ICTH has made recommendations on the standardization of methods and materials used for control of oral anticoagulants to encourage a similarity in the intensity of anticoagulant treatment that is generally used so that optimal therapeutic anticoagulant levels are attained in individual patients. In addition, other organizations have developed methods for the standardization of the prothrombin time test (Refs. *2* and *3*).

5. Risks to health: (a) Hemorrhage or thrombosis: If this device incorrectly reports the prothrombin time, hemorrhage or thrombosis could result due to the administration of an inappropriate amount of an anticoagulant drug. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of bleeding defects. Inappropriate therapy based on inaccurate diagnostic data

may place the patient at risk. Hemorrhage during surgery could result.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that prothrombin time tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Ingram, G. I. C., and M. Hills, "Reference Method for the One-Stage Prothrombin Time Test on Human Blood, International Committee for Standardization in Hematology," *Thrombosis and Haemostasis* (Stuttgart), 36:237, 1976.

2. Biggs, R., and K. W. E. Denson, "Third Report on the Standardization of the One-Stage Prothrombin Time for the Control of Anticoagulant Therapy," *Thrombosis et Diathesis Haemorrhagica*, Suppl. 26:445–450, 1967.

3. Zucker, S., et al., "Standardization of Laboratory Tests for Controlling Anticoagulant Therapy," *American Journal of Clinical Pathology*, 53:348–354, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat.1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7750 as follows:

§ 864.7750 Prothrombin time test.

(a) *Identification.* A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27681 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N–1903]

Medical Devices; Classification of Sickle Cell Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying sickle cell tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of sickle cell tests:

1. Identification: A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell anemia (a hereditary hemolytic anemia characterized by joint and abdominal pain, leg ulcers, and sickle shaped erythrocytes). The Panel identified this generic device as the "solubility hemoglobin, abnormal" and "sickle cell test."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that sickle cell tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with sickle cell tests. The Panel stated that the International Committee for standardization in Haematology (ICSH) has recommended a system for the identification of abnormal hemoglobins, including hemoglobin S (Ref. *1*) and has developed a reference preparation for the standardization of electrophoresis (Ref. *2*). The National Sickle Cell Disease Program of the National Heart and Lung Institute and the National Hemoglobinopathy Standardization Laboratory of the Center for Disease Control (CDC) recommend that cellulose acetate electrophoresis be used for sickle cell screening (Ref. *3*). The Panel also relied upon evaluations of current methodology for sickle cell testing that include electrophoretic, cytological, and chemical methods (Refs. *4* and *5*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a sickle cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that sickle cell tests be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine if reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. The CDC has published sickling and solubility tests for abnormal hemoglobins, including a discussion of conditions contributing to false positives and false negatives, the accuracy of one- and two-step tests, tests for whole blood, hemolysates, and filter paper specimens (Ref. *6*).

FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. International Committee for Standardization in Haematology, "Recommendations of a System for Identifying Abnormal Hemoglobins," *Blood*, 52(5):1065–1067, 1978.

2. International Committee for Standardization in Haematology, "Recommendations for Abnormal Haemoglobin Standard," *British Journal of Haematology*, 35:161, 1977.

3. Schmidt, R. M. and E. M. Brosious, "Evaluation of Proficiency in the Performance of Tests for Abnormal Hemoglobins," *American Journal of Clinical Pathology*, 62:664–669, 1974.

4. Schneider, R. G., and R. M. Schmidt, "Electrophoretic Screening for Abnormal Hemoglobins," *in* "Abnormal Haemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press Inc., New York, pp. 34–37, 50–55, 1975.

5. Cabannes, R., "Methodologies Suitable for Detecting Hemoglobinopathies in Developing Countries," *in* "Abnormal Hemoglobins and Thalassemia, Diagnostic Aspects," Edited by R. M. Schmidt, Academic Press Incorporated, New York, pp. 70–71, 1975.

6. Schmidt, R. M., and E. M. Brosious, "Basic Laboratory Methods of Hemoglobinopathology Detection," DHEW Publication No. (CDC) 76–8266, pp. 49–60, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7825 as follows:

§ 864.7825 Sickle cell test.

(a) *Identification.* A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell anemia (a hereditary hemolytic anemia characterized by joint and abdominal pain, leg ulcers, and sickle shaped erythrocytes).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27682 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1904]

Medical Devices; Classification of Thrombin Time Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thrombin time tests into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of thrombin time tests:

1. Identification: A thrombin time test is a device used to measure fibrinogen concentration and detect fibrin or fibrinogen split products for the evaluation of bleeding disorders. The Panel considered this generic device under the names "thrombin time test" and "thrombin."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that thrombin time tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a

reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel recommends that the product labeling be required to warn users that the reagents are unstable after reconstitution and should be used immediately.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with this test and upon a study of the thrombin time test that addresses the effects of fibrogen concentration, antithrombin activity, plasma viscosity, plasma dilution, and heat stability (ref. *1*).

5. Risks to health: (a) Hemorrhage during surgery: If this test fails to detect a bleeding defect, bleeding during surgery could result. (b) Postoperative bleeding: If this test fails to detect residual levels of heparin (an anticoagulant) in the patient's blood following surgery, hemorrhage could result. (c) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within the blood vessels). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that thrombin time tests be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk at the above address and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jim, R. T. S., "A Study of the Plasma Thrombin Time," *Journal of Laboratory and Clinical Medicine*, 50:45–60, 1957.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7875 as follows:

§ 864.7875 Thrombin time test.

(a) *Identification.* A thrombin time test is a device used to measure fibrinogen concentration and detect fibrin or fibrinogen split products for the evaluation of bleeding disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27683 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1905]

Medical Devices; Classification of Thromboplastin Generation Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thromboplastin generation tests into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of thromboplastin generation tests:

1. Identification: A thromboplastin generation test is a device used to detect and identify coagulation factor deficiencies and coagulation inhibitors.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exceptions.

3. Summary of reasons for recommendation: The Panel recommends that thromboplastin generation tests be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with this test.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a bleeding disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that thromboplastin generation tests be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7900 as follows:

§ 864.7900 Thromboplastin generation test.

(a) *Identification.* A thromboplastin generation test is a device used to detect and identify coagulation factor deficiencies and coagulation inhibitors.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27684 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1906]

Medical Devices; Classification of Partial Thromboplastin Time Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying partial thromboplastin time tests into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of partial thromboplastin time tests:

1. Identification: A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway. The Panel identified this generic type device as "partial thromboplastin time" and "partial thromboplastin time reagents, controls."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device by a high priority.

3. Summary of reasons for recommendation: The Panel recommends that partial thromboplastin time tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The partial thromboplastin time test is used for presurgical and post surgical coagulation screening, to assay for coagulation factor deficiencies, and to regulate heparin therapy (administration of the anticoagulant heparin in the treatment of venous thrombosis and pulmonary embolism). The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel believes that the labeling for this device should be required to describe the effect of various heparin concentrations on the linearity of this assay, the sensitivity of this test for the detection of factor deficiencies, and the lot-to-lot variability of this test.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with this device and on the medical literature. The Panel members noted that because the partial thromboplastin time test is a primary coagulation screening test, its accuracy is essential. The medical literature reports considerable variation in the sensitivity and performance of the partial thromboplastin time test. The College of American Pathologists' surveys of proficiency in the partial thromboplastin time test revealed an unacceptable level of variability (Ref. *1*). Because the greatest variation and imprecision occurred with the nonactivated partial thromboplastin time test, the College recommended that the use of this test be discontinued. A 1971 survey of the partial thromboplastin time test, conducted by the Center for Disease Control, reached the conclusion that no currently available reagent can give reproducible results and be equally sensitive to all intrinsic clotting factors (Ref. *2*). A 1972 study by Poller and Thomson reached the same conclusion (Ref. *3*). A 1974 report by Babson and Babson (Ref. *4*) stated that reagents using colloidal silica as an activator gave the test increased heparin sensitivity and precision. However, a 1976 study shows that a simple, accurate method for monitoring heparin therapy has yet to be developed (Ref. *5*). The Center for Disease Control is working with the International Committee for Standardization in Hematology and the International Committee on Thrombosis and Hemostasis to standardize this test.

5. Risks to health: (a) Hemorrhage or thrombosis: If this device incorrectly reports the partial thromboplastin time, hemorrhage or thrombosis may result due to the administration of an inappropriate amount of heparin. (b) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a bleeding disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. There is a risk of hemorrhage from an undiagnosed bleeding defect during surgery.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that partial thromboplastin time tests be

classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Koepke, J. A., "The Partial Thromboplastin Time in the CAP Survey Program," *American Journal of Clinical Pathology*, 63:990–994, 1975.

2. Sibley, C., J. W. Singer, and R. J. Wood, "Comparison of Activated Partial Thromboplastin Reagents," *American Journal of Clinical Pathology*, 59:581–586, 1973.

3. Poller, L. and J. M. Thomson, "The Partial Thromboplastin (Cephalin) Time Test," *Journal of Clinical Pathology*, 25:1030–1044, 1972.

4. Babson, A. L. and S. R. Babson, "Comparative Evaluation of a Partial Thromboplastin Reagent Containing a Non-Settling, Particulate Activator," *American Journal of Clinical Pathology*, 62:856–860, 1974.

5. Teien, A. N. and U. Abildgard, "On the Value of the Activated Partial Thromboplastin Time (APTT)" *in* "Monitoring Heparin Therapy," *Thrombosis and Hemostasis* (Stuttgart), 35:592–597, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart H by adding new § 864.7925 as follows:

§ 864.7925 Partial thromboplastin time test.

(a) *Identification.* A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27685 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1907]

Medical Devices; Classification of Hematology Stains

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hematology stains into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of hematology stains:

1. Identification: Hematology stains are mixtures of synthetic or natural dyes, in solution, used in staining cells of peripheral blood and bone marrow on microscope slides for diagnostic hematology. The Panel reviewed these products under the names "brilliant cresyl blue," "esterase," "Heinze body stains," "iron stains," "Ponceau stain," "reticulocyte stain," "Romanowsky stain," and "cytochemical acid phosphatase."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that hematology stains be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. However, the Panel recommends that control slides be used with every stain to assure that the stain is working properly.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. In making this recommendation, the Panel stated that it did not know of any applicable standards for stains. The Panel believes that it is an accepted fact that stains are hard to standardize and often vary from one lot to the next. It has been the Panel members' experience that 10 to 25 percent of stain lots are unusable.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in diagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Poor staining characteristics may lead to any of the following: (a) failure to detect abnormal cell types; (b) inability to differentiate reactive from malignant cells; (c) improper classification of a leukemic process; and (d) inability to classify an anemic process.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that hematology stains be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that poor staining

characteristics will rarely occur if users pay close attention to staining, rinsing, and drying slides and if they stain control slides to assure that the stains are working properly.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart I including new § 864.8030 as follows:

Subpart I—Hematology Reagents and Stains

§ 864.8030 Hematology stains.

(a) *Identification.* Hematology stains are mixtures of synthetic or natural dyes, in solution, used in staining cells of peripheral blood and bone marrow on microscope slides for diagnostic hematology.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27686 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1908]

Medical Devices; Classification of Bothrops Atrox Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Bothrops atrox reagents into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of Bothrops atrox reagents:

1. Identification: A Bothrops atrox regent is a device made from snake venom and used to determine blood fibrinogen levels to aid in the evaluation of disseminated intravascular coagulation (nonlocalized clotting in the blood vessels) in patients receiving heparin therapy (the administration of the anticoagulant heparin in the treatment of thrombosis) or as an aid in the classification of dysfibrinogenemia (presence in the plasma of functionally defective fibrinogen).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this product be a low priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends Bothrops atrox reagents be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disseminated intravascular coagulation. Inappropriate heparin therapy based on inaccurate diagnostic data may place the patient at risk. (b) Failure to detect fibrin split products (protein fragments produced by the ensymatic action of plasmin on fibrin): An erroneously short Bothrops atrox time may result in the failure to detect fibrin split products.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that Bothrops atrox reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8100 as follows:

§ 864.8100 Bothrops atrox reagent.

(a) *Identification.* A Bothrops atrox reagent is a device made from snake venom and used to determine blood fibrinogen levels to aid in the evaluation of disseminated intravascular coagulation (nonlocalized clotting in the blood vessels) in patients receiving heparin therapy (the administration of the anticoagulant heparin in the treatment of thrombosis) or as an aid in the classification of dysfibrinogenemia (presence in the plasma of functionally defective fibrinogen).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27687 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1909]

Medical Devices; Classification of Calibrators for Cell Indices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibrators for cell indices into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of calibrators for cell indices:

1. Identification: A calibrator for cell indices is a device that approximates whole blood or certain blood cells and that is used to set an instrument intended to measure mean cell volume (MCV), mean cell diameter (MCD), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), or other cell indices. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval these devices be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that calibrators for cell indices be classified into class III because this device is purported or represented to be for use in the calibration of instruments for the measurement of cell indices. This use is of substantial importance in preventing impairment of human health because the cell indices are essential to the diagnosis of certain serious blood disorders. In addition, calibrators for cell indices present a potential unreasonable risk of illness or injury if the physician relies upon inaccurate diagnostic information produced by an improperly calibrated instrument. The Panel stated that there are unanswered theoretical questions concerning the MCV and the manual and electronic methods used to obtain it. These unanswered questions preclude the possibility of assigning a true numerical value to a calibrator for the MCV or establishing a performance standard for such a calibrator. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that insufficient information exists to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The device therefore should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. Additionally, O. W. van Assendelft, M.D., Chief of the General Hematology Laboratory at the Center for Disease Control and a consultant to the Panel, stated that the technlogy for the determination of cell indices has not advanced to the stage that true values can be assigned to calibration materials for cell indices (Ref. *1*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a serious blood disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that calibrators for cell indices be classified into class III (premarket approval). The medical literature describes the source of error in the determination of the mean cell volume (MCV) (Ref. *2* and *3*). One study reported that an instrument calibrated with the reference material provided by the instrument manufacturer overestimated the MCV (Ref. *2*). A second study found that the calibration of this instrument is affected by the temperature and purity of the cell diluent employed with the instrument (Ref. *3*).

The agency believes that the device is purported or represented to be for use in the calibration of instruments for the measurement of cell indices, a use which is of substantial importance in preventing impairment of human health. The cell indices are an important diagnostic tool in the evaluation of various serious blood disorders. An elevation of the MCV is the first indication of a megaloblastic process such as megaloblastic anemia (a bone marrow disorder due to defective DNA synthesis). The MCV is also elevated in chronic alcohol abuse, bone marrow failure, sideroblastic anemia, drug-induced abnormalities in red cell production, and chronic hemolytic anemias.The MCV is reduced in iron deficiency anemia and α and β thalassemia (hereditary hemolytic anemias characterized by decreased production of the α and β hemoglobin polypeptide chains). The MCV is used to determine the cause of a decreased

demoglobin level in pregnancy. The MCH is reduced in severe iron deficiency anemia (Ref. *4*).

The agency agrees that this device presents a potential unreasonable risk of illness or injury if the physician relies upon diagnostic information produced by an improperly calibrated instrument. The agency believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Transcript of the Hematology Device Classification Panel Meeting, March 29, 1978, pp. 17–19.

2. England, J. M. and M. C. Down, "Measurement of the Mean Cell Volume Using Electronic Particle Counters," *British Journal of Haematology*, 32:403–409, 1976.

3. Young, M. and A. C. K. Lawrence, "The Influence of Extraneous Factors on Coulter S Measurement of the Mean Corpuscular Volume," *Journal of Clinical Pathology*, 28:12–15, 1975.

4. Chanarin, I., "Interpretation of Variance in the PCV," *in* "Quality Control in Haematology," Lewis, S. M. and J. F. Coster (eds.), Academic Press, New York, pp. 104–105, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8150 as follows:

§ 864.8150 Calibrator for cell indices.

(a) *Identification.* A calibrator for cell indices is a device that approximates whole blood or certain blood cells and that is used to set an instrument intended to measure mean cell volume (MCV), mean cell diamter (MCD), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), or other cell indices. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27688 Filed 9–10–79; 9:10 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1910]

Medical Devices; Classification of Calibrators for Hemoglobin and Hematocrit Measurement

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibrators for hemoglobin and hematocrit measurement into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health , Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of calibrators for hemoglobin and hematocrit measurement:

1. Identification: A calibrator for hemoglobin and hematocrit measurement is a device that approximates whole blood, red blood cells or a hemoglobin derivative and that is used to set instruments intended to measure hemoglobin, the hematocrit, or both. It is a material whose characteristics have been carefully determined.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these products be a high priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that calibrators for hemoglobin and hematocrit measurement be classified into class II because there is a need for a performance standard that prescribes for this device accceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. Additionally, O. W. van Assendelft, M.D., Chief of the General Hematology Laboratory at the Center for Disease Control and a consultant to the Panel, believes that technology has advanced to the stage where a true value can be assigned to calibration materials for hemoglobin and hematocrit measurement (Ref. *1*). The International Committee for Standardization in Hematology (ICSH) prepares and distributes a reference preparation for

hemoglobin measurement (Ref. *2*). Other reference preparations have been developed according to the ICSH protocol (Refs. *2* and *3*). The National Committee for Clinical Laboratory Standards is developing standards for hemoglobin and the hematocrit, and the World Health Organization has recommended methods for hematocrit determination (Ref. *4*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of anemia or polycythemia (a condition characterized by an increased total red cell mass). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that calibrators for hemoglobin and hematocrit measurement be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the Hearing Clerk's office (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Transcript of the Hematology Device Classification Panel Meeting, March 29, 1978, pp. 17–19.

2. International Committee for Standardization in Haematology, "Recommendations for Haemoglobinometry in Human Blood," *British Journal of Haematology*, 13 (Supp.):71, 1967.

3. Lewis, S. M., "Standards and Reference Preparations," *in* "Quality Control in Haematology," Edited by S. M. Lewis, and J. F. Coster, Academic Press, New York, pp. 82–83, 1975.

4. van Assendelft, O.W., J. F. Coster, and P. J. Crossland-Taylor, "Methods for the Determination of Packed Cell Volume," World Health Organization Document LAB/76.3.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8165 as follows:

§ 864.8165 Calibrator for hemoglobin and hematocrit measurement.

(a) *Identification.* A calibrator for hemoglobin and hematocrit measurement is a device that approximates whole blood, red blood cells, or a hemoglobin derivative and that is used to set instruments intended to measure hemoglobin, the hematocrit, or both. It is a material whose characteristics have been carefully determined.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27689 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1911]

Medical Devices; Classification of Calibrators for Platelet Counting

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Admnistration (FDA) is issuing for public comment a proposed regulation classifying calibrators for platelet counting into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Admnistration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of calibrators for platelet counting:

1. Identification: A calibrator for platelet counting is a device that approximates platelets in plasma and that is used to set a platelet counting instrument. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for these products be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that calibrators for platelet counting be classified into class III because this device is purported or represented to be for use in the calibration of automated platelet counting instruments, a use that is of substantial importance in preventing impairment of human health due to the essential nature of a platelet count in the diagnosis of bleeding disorders. In addition, calibrators for platelet counting present a potential unreasonable risk of illness or injury due to the lack of a suitable technology to assign a true numerical value to a material to be used as a platelet calibrator. This technology has been hindered by the difficulties inherent in platelet counting. Platelets are small, fragile cells that clump together and readily attach themselves to surfaces. In

addition, platelets are difficult to distinguish from dirt particles. The patient may be placed at risk if the physician relies upon inaccurate diagnostic information produced by an improperly calibrated platelet counter. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that insufficient information exists to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The device therefore should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and on the expert opinion of Lewis (Ref. *1*). The Panel stated that no calibration material has sufficient stability or reporducibility to serve as a calibrator for platelet counting. Lewis coucurs with this statement. The Panel stated that technology has not advanced to the stage that a true numerical value can be assigned to a calibration material for platelet counting.

5. Risks to health: Misdiagnosis and inapropriate therapy: Failure of the deivce to perform satisfactorily may lead to an error in the diagnosis of a platelet disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that calibrators for platelet counting be classified into class III (premarket approval). The medical literature includes reports of difficulties encountered in calibrating automated platelet-counting instruments (Refs. *2* and *3*). An instrument calibrated with reference materials provided by the instrument's manufacturer consistently produced results that were 30 percent high. Such an error would cause the instrument to give a false normal value for a thrombocytopenic blood sample (Ref. *2*). (Thrombocytopenic blood contains a reduced number of blood platelets.) The agency believes that the device is purported or represented to be for use in the calibration of automated platelet-counting instruments, a use which is of substantial importance in preventing impairment of human health. The platelet count is essential to the diagnosis of bleeding discorders. Thrombocytosis (increased platelet count) occurs in polycythemia vera (a potentially fatal disease characterized by increased total red cell mass and blood volume often accompanied by increased number of leukocytes and platelets) and chronic myelogenous leukemia (leukemia originating in the bone marrow). The platelet count is decreased in certain anemias and acute leukemia (Ref. *4*).

The agency agrees that this device presents a potential unreasonable risk of illness or injury if the physician relies upon diagnostic information produced by an improperly calibrated platelet counter. The agency believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lewis, S. M., "Standards and Reference Preparations," *in* "Quality Control in Haematology," Edited by S. M. Lewis and J. F. Coster, Academic Press, New York, pp. 91–92, 1975.

2. Delange, J. A. et al., "Automation in the Hematology Laboratory," *Journal of Clinical Chemistry and Clinical Biochemistry*, 14:485–497, 1976.

3. Rutten, W. P. F. et al., "A Systematic Investigation on the Hemalog," *Journal of Clinical Chemistry and Clinical Biochemistry* 9:387–393, 1975.

4. Brown, B. A., "Hematology: Principles and Procedures," Lea and Febiger, Philadelphia, pp. 100–101, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8175 as follows:

§ 864.8175 Calibrator for platelet counting.

(a) *Identification.* A calibrator for platelet counting is a device that approximates platelets in plasma that is used to set a platelet-counting instrument. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four Copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27690 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1912]

Medical Devices; Classification of Calibrators for Red Cell and White Cell Counting

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibrators for red cell and white cell counting into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of calibrators for red cell and white cell counting:

1. Identification: A calibrator for red cell and white cell counting is a device that approximates whole blood or red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these products be a high priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that calibrators for red cell and white cell counting be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommedation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. Additionally, O. W. van Assendelft, M.D., Chief of the General Hematology Laboratory at the Center for Disease Control and a consultant to the Panel, states that technology has advanced to the stage where a true value can be assigned to calibration materials for red cell and white cell counting (Re. *1*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a red cell or white cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that calibrators for red cell and white cell counting be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because genral controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Reference

1. Transcript of the Hematology Device Classification Panel Meeting, March 29, 1978, pp. 17–19.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8185 as follows:

§ 864.8185 Calibrator for red cell and white cell counting.

(a) *Identification.* A calibrator for red cell and white cell counting is a device that approximates whole blood or red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or fixed cells whose size, shape, concentration, and other characteristics have been carefully determined.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27691 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1913]

Medical Devices; Classification of Blood Cell Diluents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood cell diluents into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of blood cell diluents:

1. Identification: A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

2. Recommended classification: Class I (general controls.) The Panel

recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that blood cell diluents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that blood cell diluents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8200 as follows:

§ 864.8200 Blood cell diluent.

(a) *Identification.* A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27892 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1914]

Medical Devices; Classification of Lymphocyte Separation Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lymphocyte separation media into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierkshiede, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of lymphocyte separation media:

1. Identification: A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that lymphocyte separation media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that lymphocyte separation media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1). it is proposed that part 864 be amended in Subpart I by adding new § 864.8500 as follows:

§ 864.8500 Lymphocyte separation medium.

(a) *Identification.* A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27893 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1915]

Medical Devices; Classification of Red Cell Lysing Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying red cell lysing reagents into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of red cell lysing reagents:

1. Identification: A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or to remove red blood cells to facilitate the counting of white blood cells.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that red cell lysing reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that red cell lysing reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8540 as follows:

§ 864.8540 Red cell lysing reagent.

(a) *Identification.* A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations of to remove red blood cells to facilitate the counting of white blood cells.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27694 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1916]

Medical Devices; Classification of Hematology Quality Control Mixtures

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hematology quality control mixtures into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS. Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of hematology quality control mixtures:

1. Identification: A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count, (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this product be a high priority.

3. Summary of reasons for recommendation: The Hematology Device Classification Panel recommends that hematology quality control mixtures be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity,

and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that quality control mixtures are among the most critical products used in the hematology laboratory. The laboratory relies upon these products to determine that its reagents have not deteriorated and that its instruments are functioning properly. If a quality control mixture is defective, the laboratory could not know that its reagents had deteriorated or that its instruments were not functioning properly and could provide practitioners with erroneous clinical data. Use of erroneous data as the basis for a diagnosis could be hazardous to a patient's health. The development of performance standards for hematology quality control mixtures is essential to ensure consistency in the product as a quality control measure. the allowed variation in the product's stated value must not be so wide as to make that value meaningless. The Panel believes the labeling should be required to state the instruments for which its product will give valid results. Quality control materials should never be used for the calibration of an instrument. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a disease process. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. For example, in the case of platelet disorders, a patient could suffer hemorrhage because of failure to detect severe thrombocytopenia (a decrease in the number of platelets), or spontaneous thrombosis because of failure to recognize thrombocytosis (an increase in the number of platelets in the blood).

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that hematology quality control mixtures be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8625 as follows:

§ 864.8625 Hematology quality control mixture.

(a) *Identification.* A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27695 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1917]

Medical Devices; Classification of Russell Viper Venom Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Russell viper venom reagents into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of Russell viper venom reagents:

1. Identification: Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Russell viper venom reagents be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommended that the product labeling be required to state that the user should, when changing from one lot of reagent to another, check the calibration of this test for proper venom concentration.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, clinical experience with, this device. Additionally, the Panel members considered a study that suggested that this reagent be used to investigate prolonged prothrombin times (Ref. *1*) and a study of the coagulant activity of the venom (Ref. *2*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a deficiency in factor VII (the coagulation factor proconvertin). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. There is a risk of bleeding during surgery or other procedure.

Proposed Classification

The FDA agrees with the Panel's recommendation and is proposing that Russell viper venom reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hougie, C., E. M. Barrow, and J. B. Graham, "Stuart Clotting Defect I. Segregation of an Hereditary Hemorrhagic State from the Heterogeneous Group Heretofore Called 'Stable Factor' (SPCA, Proconvertin, Factor VII) Deficiency," *Journal of Clinical Investigation*, 36:485–496, 1957.

2. Macfarlane, R. G., "The Coagulant Action of Russell's Viper Venom, the Use of Antivenom in Defining Its Reaction with a Serum Factor," *British Journal of Haematology*, 7:496–511, 1961.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart I by adding new § 864.8950 as follows:

§ 864.8950 Russell viper venom reagent.

(a) *Identification.* Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27696 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1918]

Medical Devices; Classification of Blood Bank Supplies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood bank supplies into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding to the classification of blood bank supplies:

1. Identification: Blood bank supplies are general purpose devices for in vitro use in blood banking. This generic type of device includes products such as blood bank pipettes, blood grouping slides, blood typing tubes, blood typing racks, and cold packs for antisera reagents. The device does not include articles that are licensed by FDA's Bureau of Biologics.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that blood bank supplies be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, blood bank supplies which indicates that these devices are routinely used in blood banking and do not present any significant risk to health.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood bank supplies be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended by adding Subpart J including new § 864.9050 as follows:

Subpart J—Products Used in Establishments That Manufacture Blood and Blood Products

§ 864.9050 Blood bank supplies.

(a) *Identification.* Blood bank supplies are general purpose devices for in vitro

use in blood banking. This generic type of device includes products such as blood bank pipettes, blood grouping slides, blood typing tubes, blood typing racks, and cold packs for antisera reagents. The device does not include articles that are licensed by the Bureau of Biologics of the Food and Drug Administration.

(b) *Classification.* Class I (general controls.).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27697 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1919]

Medical Devices; Classification of Containers for the Collection and Processing of Blood and Blood Components

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying containers for the collection and processing of blood and blood components into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of containers for the collection and processing of blood and blood components:

1. Identification: A container for the collection and processing of blood and blood components is an empty plastic bag or plastic or glass bottle used to collect, store, or transfer blood and blood components for further processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that empty containers for the collection and processing of blood and blood components be classified into class II to provide for control of the risk of contamination of the blood or blood components placed in these containers. Contamination may be bacterial or may be due to toxic substances leached from the plastic used to construct the container. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with blood collection and processing containers.

5. Risks to health: (a) Bacterial contamination: Improper sterilization may result in bacterial contamination of the blood or blood component. (b) Emboli: The container may contain particulate matter that could cause emboli if infused into the patient's circulation. (c) Toxicity: The plastic container may leach carcinogenic or toxic materials such as plasticizers into the blood or blood component stored in it.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that containers for the collection and processing of blood and blood components be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device. The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. Blood or blood components must be administered to a patient through administration sets which contain filters to remove particulate matter, thereby minimizing the risk of emboli. The viability of blood cells stored in plastic bags is influenced by the characteristics of the plastic from which the bag is manufactured (Refs. *1, 2,* and *3*). Significant characteristics include the surface, thickness, and any substances that blood or blood components may leach from the plastic (Ref. *1*). It is known that human or animal blood will extract plasticizers such as di-2-ethylhexyl phthalate (DEHP) from polyvinyl chloride (PVC) blood bags, tubing, and medical devices (Refs. *4* and *5*). Significant amounts of DEHP have been detected in plasma prepared from whole blood stored in PVC bags at 4° C (Ref. *6*). Transfusion of blood stored in plastic bags has resulted in detectable amounts of DEHP in patients' lungs, livers, and spleens (Ref. *7*). Contact with PVC plastics or the resins, plasticizers, and stabililizers constituting these plastics has been shown to have a destructive effect on animals (Refs. *7, 8,* and *9*), biological systems (Refs. *10* and *11*), and antisera (Ref. *10*). It has not been demonstrated that the infusion of blood or blood products containing DEHP has any adverse effects on humans (Refs. *6* through *12*). However, the effects of long-term or repeated

exposure to DEHP, especially in the case of transfusion recipients who are already in a weakened state, merits continued investigation (Refs. *13* and *14*). New plastics that are developed as alternatives to PVC must be carefully evaluated for their potential for leaching toxic or carcinogenic substances (Ref. *7*). The International Organization for Standardization has developed a standard for plastics and collapsible containers for blood and blood components (Ref. *15*).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Slichter, S. J. and L. A. Harker, "Preparation and Storage of Platelet Concentrates II. Storage Variables Influencing Platelet Viability and Function," *British Journal of Haematology*, 34:403–419, 1976.

2. Murphy, S., S. N. Sayar, and F. H. Gardner, "Storage of Platelet Concentrates at 22° C," *Blood*, 35:549, 1970.

3. Mollison, P. L., "Blood Transfusion in Clinical Medicine," 5th Ed., Blackwell Scientific Publications, London, p. 65, 1972.

4. Jaeger, R. J. and R. J. Rubin, "Migration of a Phthalate Ester Plasticizer from Polyvinyl Chloride Blood Bags into Stored Human Blood and its Localization in Human Tissues," *New England Journal of Medicine*, 287(22): 1114–1118, 1972.

5. Jaeger, R. J. and R. J. Rubin, "Extraction, Localization, and Metabolism of Di-2-Ethylhexyl Phthalate from PVC Plastic Medical Devices," *Environmental Health Perspectives*, 3:95–102, 1973.

6. Valeri, C. R. et al., "Accumulation of Di-2-Ethylhexyl Phthalate (DEHP) in Whole Blood, Platelet Concentrates, and Platelet-Poor Plasma 1. Effect of DEHP on Platelet Survival and Function," *Environmental Health Perspectives*, 3:103–118, 1973.

7. Tepper, L. B., "Phthalic Acid Esters—An Overview," *Environmental Health Perspectives*, 3:179–182, 1973.

8. Boiver, R. K., S. Haberman, and P. D. Minton, "Teratogenic Effects in the Chick Embryo Caused by Esters of Phthalic Acid," *Journal of Pharmacology and Experimental Therapeutics*, 171(2):314–324, 1970.

9. Peters, J. W. and R. M. Cook, "Effects of Phthalate Esters on Reproduction in Rats," *Environmental Health Perspectives*, 3:91–94, 1973.

10. Haberman, S. et al., "Effects of Plastics and Their Additives on Human Serum Proteins, Antibodies, and Developing Chick Embryos," *Society for Plastics Engineers Journal*, 24:62–69, 1968.

11. Guess, W. L. et al., "Characterization of Subtle Toxicity of Certain Plastic Components Used in Manufacture of the Polyvinyls," *American Journal of Hospital Pharmacy*, 24:495, 1967.

12. Contreras, T. J., R. H. Sheibley, and C. Valeri, "Accumulation of Di-2-Ethylhexyl Phthalate (DEHP) in Whole Blood, Platelet Concentrates, and Platelet-Poor Plasma," *Transfusion*, 14:34, 1974.

13. Rubin, R. J. and C. A Schiffer, "Fate in Humans of the Plasticizer Di-2-Ethylhexyl Phthalate Arising from Transfusion of Platelets Stored in Vinyl Plastic Bags," *Transfusion*, 16(4):330, 1976.

14. Valeri, C. R., "Blood Banking and the Use of Frozen Blood Products," CRC Press, Inc., Cleveland, pp. 20–23, 1976.

15. International Organization for Standardization, "Plastics, Collapsible Containers for Blood and Blood Components," 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9100, to read as follows:

§ 864.9100 Container for the collection and processing of blood and blood components.

(a) *Identification.* A container for the collection and processing of blood and blood components is an empty plastic bag or plastic or glass bottle used to collect, store, or transfer blood and blood components for further processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27698 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1920]

Medical Devices; Classification of Vacuum-Assisted Blood Collection Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vacuum-assisted blood collection systems into class I (general controls). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health , Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vacuum-assisted blood collection systems:

1. Identification: A vacuum-assisted blood collection system is a device that uses a vacuum to draw blood for subsequent reinfusion.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemption.

3. Summary of reasons for recommendation: The Panel recommends that vacuum-assisted blood collection systems be Classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The panel based its recommendation upon the Panel members' knowledge of, and clinical experience with, blood collection.

5. Risks to health: (a) Collection of an incorrect amount of blood: An improperly calibrated or malfunctioning blood collection system could result in the collection of too much or too little blood. (b) Poor cell or component recovery: Drawing blood through a small opening using a vacuum may result in cell damage, such as red cell hemolysis (disruption of the cell membrane accompanied by the release of hemoglobin), during collection or processing.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that vacuum-assisted blood collection systems be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that if the operating instructions in the product labeling are followed carefully, the device will present minimal risks to health.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9125, to read as follows:

§ 864.9125 Vacuum-assisted blood collection system.

(a) *Identification.* A vacuum-assisted blood collection system is a device that uses a vacuum to draw blood for subsequent reinfusion.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27899 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1921]

Medical Devices; Classification of Processing Systems for Frozen Blood

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying processing systems for frozen blood into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of processing systems for frozen blood:

1. Identification: A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that processing systems for frozen blood be classified into class II because a performance standard is necessary to control the risk of damage to blood cells from improper freezing. A performance standard also is needed to control the risk of a hemolytic transfusion reaction in the recipient because of improper removal of glycerol from blood to be transfused. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with processing systems for frozen blood. The Panel believes that the American Association of Blood Banks' guidelines provide an excellent basis for a performance standard (Ref. *1*).

5. Risks to health: (a) Hemolytic transfusion reaction: Incomplete removal of glycerol could result in a hemolytic transfusion reaction in the recipient of the transfused blood. (b) Infusion of damaged blood or blood components: If this device fails to perform satisfactorily, the blood or blood components recovered may not be suitable for use because of damage during collection or processing. One form of damage is red cell hemolysis. Infusion of damaged blood or blood components may harm the recipient. (c) Bacterial contamination: Improper freezing may result in bacterial contamination of the blood or blood components. (d) Toxicity: The plastics in this system may leach toxic substances into the blood or blood components exposed to them.

Proposed Classification

The FDA agrees with the Panel's recommendation and is proposing that processing equipment for frozen blood be classified into class II (performance standards). The agency believes that performance standard is necessary for

this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device. The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. Glycerol has been used as a cryopreservative to protect red cells against freeze-thaw hemolysis for over 25 years (Ref. *1*). However, the addition of glycerol may result in hemolysis unless great care is taken. After thawing, the cryopreserved cells must be washed and deglycerolized. The washing process should maximize the red cell recovery and remove certain unwanted substances from the red cells. These substances include glycerol, the storage anticoagulant, plasma, white cells, platelets, certain additives, and infectious agents (Ref. *2*). Deglycerolization presents the greatest difficulty in terms of time, cost, and red cell loss (Refs. *1*, *3*, and *4*). The glycerol level should be less than 1 percent in blood to be used for transfusion. (Ref. *4*).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Association of Blood Banks." Seventh edition, Miller, W. V. et al., eds., J. B. Lippincott Co., Philadelphia, PA, pp. 47–53, 1977.

2. Contreras, R. J. and C. R. Valeri, "A Comparison of Methods To Wash Liquid-Stored Red Blood Cells Frozen With High or Low Concentrations of Glycerol," *Transfusion*, 16(6):539–565, 1976.

3. Meryman, H. T. and M. Hornblower, "A Method for Freezing and Washing Red Blood Cells Using High Glycerol Concentration," *Transfusion*, 12: 145–156, 1972.

4. Bryant, L. R. Jr., "The Large-Scale Use of Frozen Blood by the Hospital Blood Bank," *American Journal of Medical Technology*, 43(8):785–789, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9145, to read as follows:

§ 864.9145 Processing system for frozen blood.

(a) *Identification.* A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27700 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1922]

Medical Devices; Classification of Blood Group Substances of Nonhuman Origin for In Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood group substances of nonhuman origin for in vitro diagnostic use into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood group substances of nonhuman origin for in vitro diagnostic use:

1. Identification: Blood group substances of nonhuman origin for in vitro diagnostic use are materials, such as blood group specific substances prepared from nonhuman sources (e.g., pigs, cattle, and horses), used to detect, identify, or neutralize antibodies to various human blood group antigens. This generic type of device does not include materials that are licensed by FDA's Bureau of Biologics.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that blood group substances of nonhuman origin for in vitro diagnostic use be classified into class II to control the risk of transfusion reactions due to undetected antibodies in the recipient's serum. A standard prescribing acceptable ranges of sensitivity and specificity would minimize the possibility that an antibody would go undetected. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with blood group substances.

5. Risks to health: Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified, and this could result in a transfusion reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood group substances of nonhuman origin for in vitro diagnostic use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9160, to read as follows:

§ 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use

(a) *Identification.* Blood group substances of nonhuman origin for in vitro diagnostic use are materials, such as blood group specific substances prepared from nonhuman sources (e.g., pigs, cows, and horses) used to detect, identify, or neutralize antibodies to various human blood group antigens. This generic type of device does not include materials that are licensed by the Bureau of Biologics of the Food and Drug Administration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27701 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1923]

Medical Devices; Classification of Automated Blood Grouping and Antibody Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated blood grouping and antibody test systems into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated blood grouping and antibody test systems:

1. Identification: An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that automated blood grouping and antibody test systems be classified into class II to control the incubation period, frequency of cell mixing, and temperature and concentration of reagents used so that inaccurate blood grouping will be minimized. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendaton is based: The Panel based its recommendation upon the Panel members' clinical experience with blood grouping and antibody detection. The Panel believes that the American Association of Blood Banks' standards for blood grouping provide an excellent basis for the development of a performance standard.

5. Risks to health: (a) Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified. This failure could result in a transfusion reaction. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (c) Blood grouping errors: Failure of this device to perform satisfactorily may cause errors in blood grouping. This failure could result in the selection of an inappropriate blood group for transfusion and a subsequent transfusion reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated blood grouping and antibody test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard

would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9175 to read as follows:

§ 864.9175 Automated blood grouping and antibody test system.

(a) *Identification.* An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27702 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1924]

Medical Devices; Classification of Blood Grouping View Boxes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood grouping view boxes into class I (general controls). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health , Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood grouping view boxes:

1. Identification: A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that blood grouping view boxes be Classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience in antigen-antibody testing.

5. Risks to health: Inaccurate blood grouping: If the temperature of this device exceeds a certain level, antigen-antibody reactions will be affected, and inaccurate blood grouping may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood grouping view boxes be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9185, to read as follows:

§ 864.9185 Blood grouping view box.

(a) *Identification.* A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27703 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1925]

Medical Devices; Classification of Blood Mixing and Weighing Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood mixing and weighing devices into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public

comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood mixing and weighing devices:

1. Identification: A blood mixing and weighing device is a device used to mix blood or blood components by agitation or to weigh blood or blood components as they are collected.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary the reasons for recommendation: The Panel recommends that blood mixing and weighing devices be classified into class I because these are simple devices in common use that do not present any risks to health. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, blood mixing and weighing devices.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood mixing and weighing devices be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9195, to read as follows:

§ 864.9195 Blood mixing and weighing device.

(a) *Identification.* A blood mixing and weighing device is a device used to mix blood or blood components by agitation or to weigh blood or blood components as they are collected.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27704 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1926]

Medical Devices; Classification of Blood and Plasma Warming Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying non-electromagnetic blood and plasma warming devices into class II (performance standards) and electromagnetic blood and plasma warming devices into class III (premarket approval). The FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that nonelectromagnetic blood warmers be classified into class II and the electromagnetic blood warmers be classified into class III, and the recommendation of the Hematology Device Classification Panel that all blood and plasma warming devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel and the Anesthesiology Device Classification Panel, two FDA advisory committees, made the following recommendations regarding the classification of blood and plasma warming devices:

1. Identification: A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other than electromagnetic radiation, prior to administration. An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration.

2. Recommended classification: The Anesthesiology Device Classification Panel recommends that nonelectromagnetic blood warmers be classified into class II (performance

standards) and that establishing a performance standard for this device be a high priority. The Anesthesiology Device Classification Panel recommends that electromagnetic blood warmers be classified into class III (premarket approval) and that premarket approval for this device be a low priority. The Hematology Device Classification Panel recommends that all blood and plasma warming devices be classified into class II and that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel recommends that nonelectromagnetic blood warmers be classified into class II (performance standards) because the Panel believes that the characteristics of these devices need to be controlled to assure that proper blood temperature is attained and that the system is leak-free to prevent air emboli from entering the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide a reasonable assurance of the safety and effectiveness of the nonelectromagnetic blood warmer and that there is sufficient information to establish a standard to provide such assurance. The Anesthesiology Device Classification Panel recommends that the electromagnetic blood warmer be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the recipient if hemolyzed blood is infused. Because of the manner in which the radiation is emitted and reflected within the microwave warmer, the device heats blood unevenly. Uneven heating results in hot spots that can cause hemolysis (disruption of the red blood cells accompanied by release of hemoglobin). A means of eliminating this uneven heating has not been developed. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that insufficient information exists to establish a performance standard that would prevent uneven heating and thus provide reasonable assurance of the safety and effectiveness of the device. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. The Hematology Device Classification Panel recommends that blood and plasma warming devices be classified into class II to assure that a standard controls the temperature of the warmer and thus prevents damage to the blood or plasma. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the warming of blood and plasma.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Infusion of chilled, hemolyzed, or coagulated blood: If a blood and plasma warming device fails to heat blood properly, the blood may be damaged. Uneven heating, a potential problem with the electromagnetic warmer, or excessive heating, a potential problem with both the electromagnetic and the nonelectromagnetic warmers, may cause hemolysis or coagulation of the blood. If hemolyzed or coagulated blood is infused into a patient, the patient could suffer pulmonary or cerebral complications or death. If chilled blood is infused into a patient, hypothermia (abnormally reduced body temperature) or cardiac arrest may occur. (b) Air emboli: With respect to the type of nonelectromagnetic warmer that consists of a coil of plastic tubing that is placed in a water bath or electric warmer, leaks in the tubing or inadequate trapping of flushed gas may allow air emboli to enter the patient. (c) Electromagnetic interference: The radiation emitted by the electromagnetic blood and plasma warmer could produce electromagnetic interference in other medical devices, and may thus result in erroneous data and inappropriate therapy.

The Hematology Device Classification Panel identified the following risk to health: (d) Bleeding: Failure of a blood and plasma warming device to perform satisfactorily may result in overheating and damage to blood cells, components, or blood products. Overheating damages blood or denatures plasma protein by inactivating various coagulation factors. Bleeding can result in patients who receive damaged blood or plasma.

Proposed Classification

FDA agrees with both Panels' recommendations with respect to nonelectromagnetic blood and plasma warming devices and is proposing that these devices be classified into class II (performance standards). The agency has reviewed additional data and information concerning the device to determine whether a performance standard will provide reasonable assurance of the safety and effectiveness of the device. One type of nonelectromagnetic blood and plasma warmer consists of a coil of plastic tubing that is inserted into the transfusion line. The coil is either immersed in an electrically heated water bath or placed between two electrically heated warming plates. This type requires use of a long piece of tubing to warm the blood sufficiently. Pressure must be exerted to force the cold, highly viscous blood through the tubing, and the greater the length of the tubing, the more pressure is required. This pressure may hemolyze the blood. The infusion rate that can be achieved with this type of device is necessarily slow, due to the length of time required to warm the blood. Therefore, this type of device is not suitable for rapid, massive transfusions in emergency situations (Refs. *1* through *4*). Another type of nonelectromagnetic warmer heats a plastic bag of blood or plasma between two electrically heated warming plates. The agency believes that a performance standard is necessary for both types of this device because general controls alone are insufficient to contorl the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

FDA is proposing that electromagnetic blood and plasma warming devices be classified into class III (premarket approval). With respect to these devices, the agency agrees with the recommendation of the Anesthesiology Device Classification Panel that the devices be classified into class III and disagrees with the recommendation of the Hematology Device Classification Panel that the devices be classified into class II. Before deciding which Panel's recommendation to accept, the agency reviewed additional data and information concerning the device to determine whether general controls alone would provide reasonable assurance of the safety and effectiveness of the device or whether sufficient information exists to establish a performance standard to provide such assurance. Microwave blood and plasma warmers were in widespread use in the United States by the late 1960's. This type of warmer consists of a

microwave oven containing apparatus that rotates the unit of blood, a temperature sensor that shuts off the device when the temperature of the unit of blood reaches a certain range, a timer that shuts off the device after a preset time regardless of the temperature of the unit of blood, and special shielding intended to eliminate uneven heating of the unit of blood (Refs. *2* through *6*). Despite improvements designed to provide more uniform distribution of radiant energy, reports of hemolysis of units of blood began to appear by 1971 (Refs. *2, 5,* and *7*). There have been two reports of overheating due to improper placement ot the temperature sensor (Ref. *5*) and improper positioning of the unit of blood (Ref. *7*). However, hemolysis has resulted even when the manufacturer's instructions were followed precisely (Refs. *2* and *5*). In one report the temperature sensing and control apparatus were inadequate, and small units of blood, i.e., 250 to 300 milliliters, exhibited substantial hemolysis (Ref. *2*). There are two types of overheating, gross and focal, that may damage blood. Gross overheating refers to a siutation in which the average temperature of the unit of blood is excessive. The agency believes that a standard assuring proper performance of the temperature sensing and control apparatus could control this risk. Focal overheating, the occurrence of hot spots within a unit of blood due to uneven power distribution, presents a more difficult problem. Hot spots are caused by the emission of radiation from a single point in the warmer and numerous subsequent internal reflections. At certain points within the warmer, the reflected radiations interact in an additive fashion and produce hot spots that are not detected by the temperature sensor. An effective means of eleminating hot spots has yet to be developed. Because radiowave warmers are similar in design to microwave warmers, the agency believes that radiowave warmers present a similar risk of undetected hot spots, and resulting hemolysis, in units of heated blood. Furthermore, there have been few studies of the effects of microwave or radiowave heating upon blood cells. It is possible that a microwave warmer produces a population of damaged but intact erythrocytes with a shortened in vivo survival (Ref. *7*). An additional hazard related to the use of microwave blood warmers is that the personnel operating the device may be exposed to microwave radiation. Microwaves have been implicated in cataract formation (Refs. *8* and *9*) and cardiovascular disease (Ref. *10*). Like the Anesthesiology Device Classification Panel, the agency believes that the electromagnetic blood and plasma warmer presents a potential unreasonable risk of illness or injury (including death) if hemolyzed blood is transfused into a patient. The agency also believes that the device is for a use (heating blood for use in massive, emergency transfusions) that is of substantial importance in preventing impairment of human health. The agency believes that premarket approval is necessary for the device because general controls are insufficient to control this risk and thus to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is insufficient information to establish a performance standard to control this risk and thus to provide reasonable assurance of the safety and effectiveness of the device. When the electromagnetic blood and plasma warmer undergoes premarket approval, manufacturers will be required to demonstrate that their devices meet any performance standards for nonelectromagnetic blood and plasma warmers with respect to maintenance of blood temperatures and adequacy of the temperature control apparatus. If no such standard exists, these manufacturers will be required to demonstrate satisfactory performance in these respects.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Mollison, P. L., "Blood Transfusion in Clinical Medicine," Blackwell Scientific Publications, Oxford, p. 581, 1972.

2. McCullough, J. et al., "Iatrogenic Hemolysis: A Complication of Blood Warmed by a Microwave Device," *Anesthesia and Analgesia,* 51(1):102–106, 1972.

3. Restall, C. J. et al., "A Microwave Blood Warmer: A Preliminary Report," *Anesthesia and Analgesia,* 46(5):625–628, 1967.

4. duPlessis, J., A. Bull, and J. Besseling, "An Assessment of Radio Frequency Induction Heating of Bood for Massive Transfusion," *Anesthesia and Analgesia,* 46(1):96–100, 1967.

5. Arens, J. F. and G. L. Leonard, "Danger of Overwarming Blood by Microwave," *Journal of the American Medical Association,* 218(7):1045–1046, 1971.

6. Leonard, P. et al., "Microwave Warming of Bank Blood," *Anesthesia and Analgesia,* 50(2):302–305, 1971.

7. Staples, P. and P. Griner, "Extracorporeal Hemolysis of Blood in a Microwave Blood Warmer," *New England Journal of Medicine,* 285(6):317–319, 1971.

8. Zaret, M. and W. Snyder, "Cataracts and Avionic Radiations," *British Journal of Ophthalmology,* 61:380–384, 1977.

9. Zaret, M., W. Snyder, and L. Birenbaum, "Cataract After Exposure to Non-Ionizing Radiant Energy," *British Journal of Ophthalmology,* 60:632–637, 1976.

10. Zaret, M., "Potential Hazards of Hertzian Radiation and Tumors," *New York State Journal of Medicine,* 146–147, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9205, to read as follows:

§ 864.9205 Blood and plasma warming device.

(a) *Nonelectromagnetic blood or plasma warming device*—(1) *Identification.* A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other then electromagnetic radiation, prior to administration.

(2) *Classification.* Class II (performance standards).

(b) *Electromagnetic blood and plasma warming device*—(1) *Identification.* An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration.

(2) *Classification.* Class III (permarket approval).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27705 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N-1927]

Medical Devices; Classification of Cell-Freezing Apparatus and Reagents for In Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cell-freezing apparatus and reagents for in vitro diagnostic use into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cell-freezing apparatus and reagents for in vitro diagnostic use:

1. Identification: Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cell-freezing apparatus and reagents for in vitro diagnostic use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. The Panel noted that freezing red cells does not alter the antigens and any hemolysis (disruption of red cell membrane accompanied by the release of hemoglobin) that occurs is easily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with cell freezing apparatus and reagents for in vitro diagnostic use.

5. Risks to health: Blood cell damage: The red blood cells that are recovered may not be suitable for use because of damage, e.g., hemolysis, during collection or processing. Use of damaged red cells may result in inaccurate test results.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cell-freezing apparatus and reagents for in vitro diagnostic use be classified into Class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed to amend Part 864 in Subpart J by adding new § 864.9225, to read as follows:

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

(a) *Identification.* Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-27706 Filed 9-10-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 864]

[Docket No. 78N-1928]

Medical Devices; Classification of Automated Blood Cell Separators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated blood cell separators into class III (premarket approval). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee,

made the following recommendation regarding the classification of automated blood cell separators:

1. Identification: An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that automated blood cell separators be classified into class III because the device is purported or represented to be for use in the preparation of blood components for transfusion, a use that is of substantial importance in preventing impairment of human health. In addition, the device presents a potential unreasonable risk of illness or injury to the donor or the recipient. The major risk to the donor's health is that removing blood, handling the blood outside the patient's body, and returning the blood to the patient's circulation could injure the cellular components and could activate the complement system (a series of enzymatic proteins that interact to combine with the antigen-antibody complex, destroying antigen in the form of an intact cell). The Panel indicated its concern about leaks in the separator that can result in blood or pressure loss, the risk of hepatitis due to improper decontamination of the separator system between procedures, and the blood compatibility of the various segments of the separator. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that insufficient information exists to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the information provided by Dr. Thomas F. Necheles, the Panel's Chairman, and Dr. Dennis Goldfinger, a Panel member, and on the Panel members' clinical experience with this device. Dr. Necheles routinely uses automated blood cell separators to obtain white blood cells for infusion into patients. He has observed several instances in which recipient patients developed severe fevers because of the breakdown of granulocytes (leukocytes containing granules) during the pump cycle of the separator. Dr. Necheles also described several other patients' experiences with severe bleeding after infusion of white cells obtained with a blood cell separator. Dr. Goldginer, who has extensive blood-banking experience, stated that there is very little information available regarding the hazards associated with the device. He attributed this lack of information to the absence of a suitable forum for the exchange of information concerning problems with the use of automated blood cell separators.

5. Risks to health: (a) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (b) Poor cell or component recovery: If this device fails to perform satisfactorily, the blood or blood components recovered may not be suitable for use because of cell damage during collection or processing. One form of damage is red cell hemolysis (disruption of the cell membrane accompanied by the release of hemoglobin). (c) Electrical shock: The user faces the risk of electrical shock from the electrical system of the device. (d) Adverse donor reactions: If the device fails to perform satisfactorily, the following donor reactions may occur: (1) shock resulting from blood loss; (2) abdominal pain due to infection or the sequestering of damaged cells by organs such as the liver or spleen; (3) toxic reaction to high levels of anti-coagulants such as citrate or heparin that the instrument adds to the blood before it is returned to the donor; (4) a stress reaction due to the removal or loss of blood; (5) thrombosis due to activation of clotting factors by air or surfaces within the device; (6) fever or local infection due to bacterial contamination of the blood returned to the donor; and (7) a susceptibility to hemorrhage due to the loss of platelets.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated blood cell separators be classified into class III (premarket approval). The agency has obtained additional data and information concerning automated blood cell separators. Moriau, De Bruyere, and Bellenot (Ref. *1*) recommend that the donor's blood pressure and electrocardioscopic and fluid balance changes be monitored and that the plasma replacement fluids contain an appropriate amount of calcium and be free of hepatitis antigen. Sterilization of the cell separator bowl is also a concern (Ref. *2*). There have been instances of thromboembolism in white cell donors due to platelet-white cell aggregates (Ref. *3*). The automated blood cell separator must also meet the requirements of 21 CFR Part 606, relating to good manufacturing practices for blood and blood components, specifically § 606.65, which requires that all surfaces which contact the blood or blood component be sterile, pyrogen-free, and not have an adverse effect upon the blood or blood component (Ref. *4*). The agency believes that the device is purported or represented to be for use in the preparation of blood components for transfusion, a use that is of substantial importance in preventing impairment of human health. The agency believes that the device presents a potential unreasonable risk of illness or injury because of the possible adverse donor reactions and the possibility of delivering altered, damaged, or contaminated blood or blood components to the recipient. The agency believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Moriau, M., M. De Bruyere, and C. Bellenot, "Granulocyte Collections From Normal Donors Using the Continuous Flow Centrifuge," *in* "Leukocytes: Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London, pp. 88–96, 1975.

2. Cartledge, K. W., "Problems in the Sterilization of Cell Separator Bowls," *in* "Leukocytes: Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London pp. 43–45, 1975.

3. Oon, C. J. and J. R. Hobbs, "Medical Problems in Donors on Treatment Using the Continuous Flow Blood Separator," *in* "Leukocytes: Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London, pp. 576–577, 1975.

4. Code of Federal Regulations, 21 CFR Part 606—Current Good Manufacturing Practices for Blood and Blood Components, Subpart D—Equipment § 606.65.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9245, to read as follows:

§ 864.9245 Automated blood cell separator.

(a) *Identification.* An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27707 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1929]

Medical Devices; Classification of Blood Bank Centrifuges for In Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood bank centrifuges for in vitro diagnostic use into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It it proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood bank centrifuges for in vitro diagnostic use:

1. Identification: A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that blood bank centrifuges for in vitro diagnostic use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with blood bank centrifuges.

5. Risks to health: (a) Transfusion reaction: Failure of this device to perform satisfactorily may cause errors in blood grouping. This failure could result in the selection of an inappropriate blood group for transfusion and a subsequent transfusion reaction. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood bank centrifuges for in vitro diagnostic use be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that if this centrifuge is operated according to the instructions in the labeling, and if blood samples are handled properly, the risks to health presented by the device are minimal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9275, to read as follows:

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

(a) *Identification.* A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27708 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1930]

Medical Devices; Classification of Automated Cell-Washing Centrifuges for Immuno-Hematology

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated cell-washing centrifuges for immuno-hematology into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of automated cell-washing centrifuges for immuno-hematology:

1. Identification: An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that automated cell-washing centrifuges for immuno-hematology be classified into class II to assure, by controlling the amount of saline used to wash the cells and the length of the spin, wash, and decant cycles, that the cells and sera prepared are free of interfering substances that may invalidate test results. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficent information to establish a standard to provide such assurance.

4. Summary of data upon which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with the cell-washing centrifuge for immuno-hematology.

5. Risks to health: (a) Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified. This failure could result in a transfusion reaction. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated cell-washing centrifuges for immuno-hematology be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. The American Association of Blood Banks (AABB) has made recommendations concerning automated cell washers (Ref. *1*). The AABB notes that the stream of saline used to resuspend the pellet of cells must be directed so that the cells are fully resuspended without creating a large amount of foam that may cause cross contamination. The fluid must be decanted from the cell pellet so that there are no residual amounts of serum that might interfere with further testing. The agency believes that the AABB recommendations will provide a basis for the establishment of a performance standard. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

"Technical Manual of the American Association of Blood Banks," 7th Ed., Miller, W. V., et al., eds., J. B. Lippincott Co., Philadelphia, pp. 298–301, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9285 as follows:

§ 864.9285 Automated cell-washing centrifuge for immuno-hematology.

(a) *Identification.* An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27709 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1931]

Medical Devices; Classification of Automated Coombs Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated Coombs test systems into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the

device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated Coombs test systems:

1. Identification: An automated Coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is uesd for the diagnosis of hemolytic disease of the newborn and autoimmune hemolytic anemia. The test is also used in crossmatching and investigating transfusion reations and drug-induced red cell sensitization.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that automated Coombs test systems be classified into class II, to assure by controlling the incubation period, the incubation temperature, the suspending medium, and the concentration of the cell suspension, that the device detects and accurately identifies antibodies. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with automated Coombs testing systems. The Panel believes that the American Association of Blood Banks' guidelines for Coombs testing provide an excellent basis for the development of a performance standard (Ref. *1*).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hemolytic disease of the newborn or autoimmune hemolytic anemia. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that automated Coombs test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

"Technical Manual of the American Association of Blood Banks," 7th Ed., Miller, W. V., et al., eds., J. B. Lippincott Co., Philadelphia, pp. 156–165, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) it is proposed that Part 864 be amended in Subpart J by adding new § 864.9300 to read as follows:

§ 864.9300 Automated Coombs test system.

(a) *Identification.* An automated coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is used for the diagnosis of hemolytic disease of the newborn, and autoimmune hemolytic anemia. The test is also used in crossmatching and in investigating transfusion reactions and drug-induced red cell sensitization.

(b) *Classification. Class II (performance standards).*

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27710 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1932]

Medical Devices; Classification of Copper Sulfate Solutions for Specific Gravity Determinations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying copper sulfate solutions for specific gravity determinations into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. Its is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of copper sulfate solutions for specific gravity determinations:

1. Identification: A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: the Panel recommends that copper sulfate solution for specific gravity determinations be classified into class I because the Panel believes the general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel stated that this is a very simple test requiring only that a drop of blood be placed in a copper sulfate solution of known specific gravity. If the drop sinks within 15 seconds, the specific gravity of the blood exceeds that of the solution. If the drop raises to the surface within 15 seconds, the specific gravity of the blood is less then that of the solution.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, the device.

5. Risks to health: Improper donor selection: An inaccurate specific gravity determination could result in the selection of a potential blood donor with an unsuitable hemoglobin level.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that copper sulfate solution for specific gravity determinations be classified into class I (general controls), with no exemptions. The agency believes that gerneral controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9320 to read as follows:

§ 864.9320 Copper sulfate solution for specific gravity determinations.

(a) *Identification.* A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27711 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1933]

Medical Devices; Classification of Stabilized Enzyme Solutions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stabilized enzyme solutions into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of stabilized enzyme solutions:

1. Identification: A stabilized enzyme solution is a reagent used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelin, ficin, and trypsin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that stabilized enzyme solutions be classified into class II (performance standards) because a performance standard can assure that enzyme solutions are reactive. Nonreactive enzyme solutions present the risk of inaccurate results. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that

there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' personal knowledge of, and clinical experience with, these solutions.

5. Risks to health: Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified resulting in a transfusion reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that stabilized enzyme solutions be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. The American Association of Blood Banks (AABB) has made recommendations regarding stabilized enzyme solutions (Ref. *1*). The AABB notes that the potency of enzyme solutions varies. Enzyme solutions lose their activity with age and mask antigenic determinants such as those of the Lutheran, MNS, and Duffy blood group systems. Other important factors in the potency of enzyme solutions include the pH of the solution, the length the red cell-enzyme incubation period, and the enzyme concentration. The agency believes that a performance standard is necessary for the device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Association of Blood Banks," 7th Ed., Miller, W. V., et al., eds., J. B. Lippincott Co., Philadelphia, pp. 168, 325–328, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9400, to read as follows:

§ 864.9400 Stabilized enzyme solution.

(a) *Identification.* A stabilized enzyme solution is a reagent used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelin, ficin, and trypsin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27712 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1934]

Medical Devices; Classification of Systems for the Identification of Hepatitis B Antigen

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying systems for the identification of hepatitis B antigen into class I (general controls). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of systems for the identification of hepatitis B antigen:

1. Identification: A system for the identification of hepatitis B antigen is a device that consists of the equipment and reagents necessary for the detection of hepatitis B antigen. Hepatitis B antigen is usually detected by radioimmunoassay, reversed passive hemagglutination, counterelectrophoresis, or latex agglutination. The device does not include articles that are licensed by the Bureau of Biologic of the Food and Drug Administration.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that systems for the identification of hepatitis B antigen be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with hepatitis B antigen detection.

5. Risks to health: (a) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection. (b) Radiation hazard: The user may be exposed to radiation from radioisotopes that are a part of this device. (c) Electrical shock: If the device malfunctions, the user faces the risk of

electrical shock from the electrical system of the electrophoresis equipment used to detect hepatitis B antigen.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that systems for the identification of hepatitis B antigen be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that if users carefully follow the instructions in the labeling for the use of these systems, and if the blood samples are handled properly, the risks described above will be minimized.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9500 to read as follows:

§ 864.9500 System for the identification hepatitis B antigen.

(a) *Identification.* A system for the identification of hepatitis B Antigen is a device that consists of the equipment and reagents necessary for the detection of hepatitis B antigen. Hepatitis B antigen is usally detected by radioimmunoassay, reversed passive hemagglutination, counterelectrophoresis, or latex agglutination. The device does not include articles that are licensed by the Bureau of Biologics of the Food and Drug Administration.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27713 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1935]

Medical Devices; Classification of Lectins and Protectins

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lectins and protectins into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lectins and protectins:

1. Identification: Lectins and protectins are proteins from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are used to detect blood group antigens for in vitro diagnostic purposes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lectins and protectins be classified into class II because a performance standard is necessary to assure the reactivity and specificity of these substances. Nonspecific or nonreactive substances present the risk of incorrect blood grouping. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation upon the Panel members' clinical experience with lectins and protectins.

5. Risks to health: Transfusion reaction: Failure of this device to perform satisfactorily may cause errors in blood grouping, resulting in the selection of an inappropriate blood group for transfusion and in a subsequent transfusion reaction.

Proposed Classification

FEA agrees with the Panel recommendation and is proposing that lectins and protectins be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. The medical literature concerning lectins and protectins indicates that these substances lose their stability and specificity with age (Ref. 1). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by

interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

Abelson, N. M., "Topics in Blood Banking," Lea and Febiger, Philadelphia, p. 51, 1974

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9550, to read as follows:

§ 864.9550 Lectins and protectins.

(a) *Identification.* Lectins and protectin are proteins derived from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are used to detect blood group antigens for in vitro diagnostic purposes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27714 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1936]

Medical Devices; Classification of Environmental Chambers for Storage of Platelet Concentrate

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying environmental chambers for storage of platelet concentrate into class II (performance standards). The FDA is also publishing the recommendations of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of environmental chambers for storage of platelet concentrate:

1. Identification: An environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that environmental chambers for storage of platelet concentrate be classified into class II because a performance standard is necessary to assure that the platelets are held within a certain temperature range, thus avoiding damage to the platelets. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members; knowledge of, and clinical experience with, platelets and platelet storage.

5. Risks to health: Infusion of damaged blood or blood components: Failure of the device to perform satisfactorily may result in damage to platelets because of overheating. Platelets deteriorate rapidly when the storage temperature rises to an excessively high temperature. Infusion of damaged platelets may cause serious harm to a patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that environmental chambers for storage of platelet concentrate be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. Proper storage temperature to maximize platelet viability is the subject of considerable controversy (Ref. *1*). Certain groups advocate storage at 22° C with gentle agitation, while other groups recommend 4° C with no agitation (Refs. *2* through *4*). Federal regulations allow either method of storage (Ref. *5*). Regardless of the method of storage, platelet concentrates may be stored for only 72 hours (Refs. *1* and *6*). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Assoication of Blood Banks," 7th Ed., Miller, W. V., et al., eds., Philadelphia, p. 44, 1977.

2. Slichter, S. J. and L. A. Harker, "Preparation and Storage of Platelet Concentrates. II. Storage Variables Influencing Platelet Viability and Function," *British Journal of Haematology*, 34:403–419, 1976.

3. Murphy, S., S. N. Sayar, and F. H. Gardner, "Storage of Platelet Concentrates at 22° C," *Blood*, 35:549, 1970.

4. Becker, G. A. et al., "Studies of Platelet Concentates Stored at 22° C and 4° C." *Transfusion*, 13:61, 1974.

5. 21 CFR Part 640, Subpart C—Platelet Concentrate (Human) § 640.25(a) *Storage.*

6. 21 CFR Part 610, Subpart F—Dating Period Limitations, § 610.53 *Dating periods for specific products.*

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9575 as follows:

§ 864.9575 Environmental chamber for storage of platelet concentrate.

(a) *Identification.* An environmental chamber for storage of platelet concentate is a device used to hold platelet-rich plasma within a preselected temperature range.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27715 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1937]

Medical Devices; Classification of Potentiating Media for In Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying potentiating media for in vitro diagnostic use into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of potentiating media for in vitro diagnostic use:

1. Identification: Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that potentiating media for in vitro diagnostic use be classified into class II (performance standards) because of the need to control such characteristics as the incubation time, concentration, and pH of these media. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, potentiating media for in vitro diagnostic use.

5. Risks to health: Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified, or a blood grouping error may result. This failure could result in the selection of an inappropriate blood for transfusion and in a subsequent transfusion reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that potentiating media for in vitro diagnostic use be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. Antigen-antibody reactions are influenced by factors such as temperature, incubation time, the pH and ionic strength of the reaction medium, and the antigen-antibody ratio (Ref. *1*). Reducing the ionic strength of the reaction medium enhances the binding of antibody to red cell antigens (Ref. *1*). One form of potentiating medium, a low ionic strength solution (LISS), reduces the required incubation time and is superior to albumin in its ability to suspend red cells. The LISS and serum must be present in equal proportions. A large excess of LISS lowers the ionic strength and causes false positives, while an excess of serum increases the ionic strength and decreases the sensitivity of the agglutination test. To be effective, LISS should be stored at 4° C and kept free of microorganisms (Ref. *2*). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Association of Blood Banks," 7th ed., Miller, W.V., et al., eds., J. B. Lippincott Philadelphia, pp. 147–150, 1977.

2. Moore, H. C., and P. L. Mollison, "Use of a Low-Ionic Strength Medium in Manual Tests for Antibody Detection," *Transfusion*, 16(4):291–296, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9600, to read as follows:

§ 864.9600 Potentiating media for in vitro diagnostic use.

(a) *Identification.* Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27716 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1938]

Medical Devices; Classification of Quality Control Kits for Blood-Banking Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying quality control kits for blood-banking reagents into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of quality control kits for blood-banking reagents:

1. Identification: A quality control kit for blood-banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that quality control kits for blood-banking reagents be classified into class II because a performance standard is necessary to control the risk of inaccurate test results due to lack of specificity, potency, or reactivity of the cells and reagents. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and experience in, blood banking.

5. Risks to health: (a) Transfusion reaction: If this device fails to perform satisfactorily, clinically significant antibodies may not be detected and identified, resulting in a transfusion reaction. (b) Hepatitis infection: Exposure of the user, donor, or patient to blood, blood products, or blood aerosols presents a risk of hepatitis infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that quality control kits for blood-banking reagents be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be assured by a performance standard. The American Association of Blood Banks' standards require that reagents be tested at regular intervals (Ref. *1*). Antisera being tested should react with red cells possessing weak antigenic determinants (Ref. *2*). Similarly, reagent red cells should detect weak antibodies. Testing should employ both negative and positive controls. Detailed procedures, including avidity and dilution methodologies, have been developed for quality control testing (Refs. *1* and *3*). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Association of Blood Banks," 7th Ed., Miller, W. V., et al., eds., J. C. Lippincott Co., Philadelphia, pp. 283–287, 1977.

2. Abelson, N. M., "Topics in Blood Banking," Lea and Febiger, Philadelphia, p. 45, 1974.

3. Myhre, B. A., "Quality Control in Blood Banking," John Wiley and Sons, Inc., New York, pp. 225–227, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9650 as follows:

§ 864.9650 Quality control kit for blood-banking reagents.

(a) *Identification.* A quality control kit for blood-banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27717 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1939]

Medical Devices; Classification of Blood Storage Refrigerators and Blood Storage Freezers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood storage refrigerators and blood storage freezers into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation for the classification of blood storage refrigerators and blood storage freezers:

1. Identification: A blood storage refrigerator and a blood storage freezer are devices used to preserve blood and blood products by storing them at cold or freezing temperatures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that blood storage refrigerators and freezers be classified into class II because a performance standard is necessary to control the risk of damage to blood or blood products by assuring that the device maintains the proper temperature. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel believes that the American Association of Blood Banks standards on blood storage refrigerators and freezers (Ref. *1*) provide an excellent basis for the establishment of a performance standard.

5. Risks to health: Heat damage: Failure of the device to perform satisfactorily may result in damage to blood cells, components, or blood products because of overheating.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood storage refrigerators and blood storage freezers be classified into class II (performance standards). The agency has obtained additional data and information on the device to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. The American Association of Blood Banks' standards specify the allowable temperature range for refrigerators and require circulating fans, interior lighting, recording thermometers, and an audible and/or visible alarm with its own electrical system (Ref. *1*). The storage temperature for frozen blood is important in assuring its stability. Blood frozen in a high glycerol procedure is stable over a relatively wide temperature range, but low glycerol cryo-preservation requires that blood be maintained at temperatures below minus 100° C, or complete hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) will result (Ref. *2*). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Technical Manual of the American Association of Blood Banks," 7th Ed., Miller, W. V., et al., eds., J. B. Lippincott Co., Philadelphia, pp. 57–59, 1977.

2. Abelson, N. M., "Topics in Blood Banking," Lea and Febiger, Philadelphia, p. 35, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9700, to read as follows:

§ 864.9700 Blood storage refrigerator and blood storage freezer.

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979, submit to the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27718 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1940]

Medical Devices; Classification of Heat-Sealing Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heat-sealing devices into class I (general controls) The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation The Hematology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of heat-sealing devices:

1. Identification: A heat-sealing device is a device that uses heat to seal plactic bags containing blood or blood components.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The panel recommends that heat-sealing devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and efffectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' knowledge of, and clinical experience with, heat-sealing devices.

5. Risks to health: (a) Heat damage: Failure of the device to perform satisfactorily may result in damage to blood cells, components, or blood products because of overheating. (b) Bacterial contamination: Improper sealing may result in bacterial contamination of the blood cells, components, or blood products stored in the bag.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that heat-sealing devices be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that if the manufacturer's directions for use specify the proper temperature range and the proper technique for sealing a blood bag, and if the user follows these directions, the risk of the bag contents being damaged or contaminated will be minimal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9750, to read as follows:

§ 864.9750 Heat-sealing device.

(a) *Identification.* A heat-sealing device is a device that uses heat to seal plastic bags containing blood or blood components.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before November 13, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27719 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 864]

[Docket No. 78N–1942]

Medical Devices; Classification of Transfer Sets

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transfer sets into class II (performance standards). The FDA is also publishing the recommendation of the Hematology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by November 13, 1979. It is proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William C. Dierksheide, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7234.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Hematology Device Certification Panel, an FDA advisory committee, made the following recommendation regarding the classification of transfer sets:

1. Identification: A transfer set is a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that transfer sets be classified into class I because this is a simple device in common use and does not present any unreasonable risks to health. The Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data upon which recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, transfer sets.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that transfer sets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk of bacterial contamination or the risk that toxic or carcinogenic substances will leach into the blood or blood components that contact these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency has obtained additional data and information to determine whether general controls or performance standards are appropraite for the device and whether reasonable assurance of the safety and effectiveness of the device can be provided by a performance standard. Human blood is capable of extracting plasticizers such as di-2-ethylhexyl phthalate (DEHP) from medical-grade plastic tubing, and these plasticizers are subsequently transfused into the patient (Refs. *1* and *2*). Contact with polyvinyl chloride (PVC) plastics or the resins, plasticizers, and stabilizer constituting these plastics has been shown to have a destructive effect on animals (Refs. *3*, *4*, and *5*), biological systems (Refs. *6*, and *7*), and antisera (Ref. *6*). It has not been demonstrated that infusion of blood or blood products containing DEHP has had any adverse effects on humans (Refs. *8*, *9*). However, the effects of long term or repeated exposure to DEHP, especially in the case of transfusion recipients, who are already in a weakened state, merits continued investigation (Refs. *10*, and *11*). New plastics that are developed as alternatives to PVC must be carefully evaluated with respect to their potential for leaching toxic or carcinogenic substances (Ref. *3*). The International Organization for Standardization's standards for plastics and collapsible containers for blood and blood components (Ref. *12*) also addresses transfer sets.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jaeger, R. J. and R. J. Rubin, "Migration of Phthalate Ester Plasticizer from Polyvinyl Chloride Blood Bags into Stored Human Blood and its Localization in Human Tissues," *New England Journal of Medicine*, 287(22):1114–1118, 1972.

2. Jaeger, R. J. and R. J. Rubin, "Extraction, Localization, and Metabolism of Di-2-Ethylhexyl Phthalate from PVC Plastic Medical Devices," *Environmental Health Perspectives*, 3:95–102, 1973.

3. Tepper, L. B., "Phthalic Acid Esters—An Overview," *Environmental Health Perspectives* 3:179–182, 1973.

4. Bower, R. K., S. Haberman, and P. D. Minton, "Teratogenic Effects in the Chick Embryo Caused by Esters of Phthalic Acid," *Journal of Pharmacology and Experimental Therapeutics*, 171(2):314–324, 1970.

5. Peters, J. W. and R. M. Cook, "Effects of Phthalate Esters on Reproduction in Rats," *Environmental Health Perspectives*, 3:91–94, 1973.

6. Haberman, S., et al., "Effects of Plastics and Their Additives on Human Serum Proteins, Antibodies, and Developing Chick Embryos," *Society for Plastics Engineers Journal*, 24:62–69, 1968.

7. Guess, W. L. et al., "Characterization of Subtle Toxicity of Certain Plastic Components Used in Manufacture of the Polyvinyls," *American Journal of Hospital Pharmacy*, 24:495, 1967.

8. Valeri, C. R. et al., "Accumulation of Di-2-Ethylhexyl Phthalate (DEHP) in Whole Blood, Platelet Concentrates, and Platelet-Poor Plasma 1. Effect of DEHP on Platelet Survival and Function," *Environmental Health Perspectives*, 3:103–118, 1973.

9. Contreras, T. J., R. H. Sheibley, and C. Valeri, "Accumulation of Di-2-Ethylhexyl Phthalate (DEHP) in Whole Blood, Platelet Concentrates, and Platelet-Poor Plasma," *Transfusion*, 14:34, 1974.

10. Rubin, R. J. and C. A. Schiffer, "Fate in Humans of the Plasticizer Di-2-Ethylhexyl Phthalate Arising from Transfusion of Platelets Stored in Vinyl Plastic Bags," *Transfusion*, 16(4):330, 1976.

11. Valeri, C. R., "Blood Banking and the Use of Frozen Blood Products," CRC Press, Inc., Cleveland, pp. 20–23, 1976.

12. International Organization for Standardization, "Plastics, Collapsible Containers for Blood and Blood Components," 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 864 be amended in Subpart J by adding new § 864.9875, to read as follows:

§ 864.9875 Transfer set.

(a) *Identification.* A transfer set is a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before November 13, 1979 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–27720 Filed 9–10–79; 8:45 am]

BILLING CODE 4110–03–M